S. Hrg. 103–679

MATERIALS SUPPLIER LIABILITY AND THE COMING CRISIS IN AVAILABILITY OF LIFE-SAVING MEDICAL DEVICES

Y 4. G 74/9: S. HRG. 103-679

Materials Supplier Liability and th...

HEARING

BEFORE THE

SUBCOMMITTEE ON REGULATION AND GOVERNMENT INFORMATION

OF THE

COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

MAY 20, 1994

Printed for the use of the Committee on Governmental Affairs

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MATERIALS SUPPLIER LIABILITY AND THE COMING CRISIS IN AVAILABILITY OF LIFE-SAVING MEDICAL DEVICES

FRIDAY, MAY 20, 1994

U.S. SENATE,
SUBCOMMITTEE ON REGULATION AND GOVERNMENT INFORMATION, COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:35 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Joseph I. Lieberman, Chairman of the Subcommittee, presiding.

OPENING STATEMENT OF SENATOR LIEBERMAN

Senator LIEBERMAN. Good morning, and welcome to the hearing.

This morning our Subcommittee on Regulation and Government Information turns its attention to what could be a major threat to many of the miracles of modern medicine. Over the next 2 years, health care as we know it in America could be radically transformed, and I am not talking for the moment about health care reform legislation that is being considered in this Congress. I am talking about the fact that the makers of many of the life-saving medical devices that we take for granted today may no longer be able to buy the raw materials and components that are necessary to produce their products. This is a public health time bomb, and it is ticking, and the lives of real people are going to be lost if it explodes.

What could cause such a public health catastrophe? I am afraid that the answer is our product liability system, out of control, which makes it too easy to bring lawsuits against raw materials suppliers and too costly for those suppliers to defend themselves even if and when they ultimately win. Now those suppliers are concluding that the costs of defending lawsuits involving medical products is too high in comparison to the money they are making by selling those products to the manufacturers of implantable medical devices. In other words, for the raw materials suppliers, it just is not worth it to be in this business anymore.

How could this be? Well, a recent study by a group called Aronoff Associates paints what I would describe as a clear but dismal picture. That study surveyed the markets for polyester yarn, resins such as DuPont's Teflon, and Polyacetal resin such as DuPont's Delrin. Aronoff found that sales of these raw materials for use in manufacturing implantable medical devices was just a tiny per-

centage—0.006 percent—of the overall market, $606,000 out of total annual sales that equal over $11 billion.

In return for that extra $606,000 in total annual sales, however, raw materials suppliers have faced potentially huge liability-related costs, even if they never lose a lawsuit. Let me give you one example, and it is a notorious example. A company named Vitek manufactured an estimated 26,000 jaw implants, using in each implant 5 cents' worth, a nickel's worth of DuPont Teflon. The device was developed, designed, and marketed by Vitek, which was not at all related to DuPont. It was a separate company. But when those implants began to fail, Vitek declared bankruptcy, and the patients sued DuPont. DuPont's record in court on Vitek-related claims so far has been astounding, 258 wins and only 1 loss, but the cost has been equally astounding and staggering.

Aronoff Associates estimates that DuPont alone was spending at least $8 million a year over the past 5 to 6 years to defend these lawsuits, based on the sale of an item worth a nickel for each implant.

To put this in perspective, DuPont's estimated legal costs in these cases for just 1 year would buy a 13-year supply of DuPont Dacron polyester, Teflon, and Delrin for all U.S. makers of all implantable medical devices, not just the makers of jaw implants, which were the source of the lawsuit.

Now, faced with this cost-benefit picture, as we will hear, DuPont decided in January of 1993 to stop selling its products to manufacturers of permanently implantable medical devices. At that time, DuPont said it would only permit manufacturers to purchase a year's supply, based on historical buying patterns. DuPont has subsequently allowed manufacturers to purchase up to 3 years of raw materials.

One supplier's decision—that is, DuPont, as I have described it—might not be so troublesome except that there is no reason to believe that the economics will be any different for any of the suppliers around the world. One of our witnesses today, in fact, has already contacted 15 alternate suppliers of polyester yarn worldwide. All were interested in selling raw materials, except for use in products made and used in the United States. Now, that is an outrageous result, and unacceptable.

What is at stake here? Well, without raw materials, you cannot make a final product. I have a heart valve here that I want to show, if it is visible. The valve is the metal part in the middle. Around the edge of the valve is a sleeve of polyester fabric. It is this sleeve—here you have a tag that is sewn into the sleeve. It is this sleeve that, as I understand it, is the point of connection between the valve and the rest of the heart. In other words, the surgeon sews through the fabric to attach this valve to the heart. Without the valve, the patient will probably die prematurely.

Take, for example, a pacemaker. Pacemakers are installed—again, I do not know how many have seen a pacemaker. This is a pacemaker which is installed, as I understand it, under the skin. They are installed in patients whose hearts no longer generate enough of an electric pulse to get the heart to beat. To keep the heart beating, a pacemaker is connected to the heart with wires. These wires have silicone rubber insulation. This is literally a life-

saving wire. It is a simple piece of silicone rubber that connects the pacemaker to the heart. Unfortunately, the suppliers of this rubber insulation have begun to withdraw from the market for the same reasons that I have just cited: worry about legal liability costs. Without the pacemaker and its leads, again, sadly, the patient will probably die prematurely. With the pacemaker, the patient can live for decades.

Take still a third example. We are going to hear today from Thomas Reily, a 9-year-old boy from Houston, Texas, who suffers from hydrocephalus, a condition in which fluid accumulates around the brain. A special shunt enables Tom to live a pretty normal life. But continued production of that shunt is in doubt because of the raw materials suppliers who are concerned about the potential cost of product liability lawsuits.

We are also going to hear today from Peggy Phillips of Falls Church, Virginia, whose heart has stopped beating twice, I gather, because of fibrillation. Today, she also lives an active, normal life because she has an implanted automatic defibrillator. Again, critical components of the defibrillator may no longer be available because of potential product liability costs.

We simply cannot allow Tom Reily and Peggy Phillips and the 7.4 million other people who owe the quality of their lives to modern medical devices to become casualties of an outmoded legal liability system. If the economics of supplying raw materials to the implantable medical device makers is as bad as it seems, then I think it is imperative that we act. We cannot expect raw materials suppliers to continue to serve the medical device market out of the goodness of their hearts, notwithstanding the liability-related costs. We need to reform our product liability laws, to give these raw materials suppliers some assurance that, unless there is real evidence that they were responsible for putting a defective device on the market, they cannot be sued simply in the hopes that their deep pockets will fund legal settlements.

I have long believed that the liability reform that we are talking about here in Congress could be both pro-consumer and pro-business. I believe that the testimony we are going to hear this morning proves this once again. When fear of liability suits and litigation costs drives valuable life-saving products off the market because their makers cannot get the raw materials to make those products, consumers obviously lose. When companies must divert money from developing new life-saving products to replace old sources of raw materials supply, consumers again lose. When one company must spend millions to defend itself in lawsuits over a product it did not design or make, for which it simply provided a very inexpensive raw material ingredient, consumers are the ones who suffer. I think this morning's hearing dramatically illustrates that efforts to increase compensation for the injured, if the system is allowed to go out of control, can come at an unacceptably high cost to society.

Based on the testimony that we will hear this morning, which I have gone over in some detail, I am committed to forging a solution that will head off this threat to our national public health. This morning the Subcommittee is, in fact, releasing a staff draft of a possible legislative response to this crisis. I plan to introduce a bill

shortly, a final bill, after the Memorial Day recess, with the hopes that Congress will be able to act quickly.

In my opinion, the patient, which in this case is the miraculous modern medical device industry, is in critical condition, and we really need to perform some emergency legislative surgery. Delay could quite literally be deadly.

PREPARED STATEMENT OF SENATOR LIEBERMAN

Good morning. This morning the Subcommittee on Regulation and Government Information turns its attention to what could be a major threat to many of the miracles of modern medicine. Over the next 2 years, health care as we know it could be radically transformed, not by health care reform legislation, but because the makers of many of the life-saving medical devices that we take for granted today may no longer be able to buy the raw materials and components necessary to produce their products This is a public health time bomb—and it is ticking.

What could wreak this public health catastrophe? The answer appears to be an out-of-control product liability system which makes it too easy to bring suits against raw materials suppliers, and too costly for those suppliers to defend themselves even when they ultimately win. Those suppliers have begun to decide that the costs of defending lawsuits involving medical products is too high to justify selling raw materials to the makers of implantable medical devices. For those suppliers, it just isn't worth it.

How could this be? A recent study by Aronoff Associates paints a pretty clear, but dismal, picture. That study surveyed the markets for polyester yarn, resins such as DuPont's Teflon, and polyacetal resin such as DuPont's Delrin. Aronoff found that sales of these raw materials for use in manufacturing implantable medical devices was just a tiny percentage (0.006 percent) of the overall market, $606,000 out of total sales of over $11 billion.

In return for that extra $606,000 in total annual sales, however, raw materials suppliers face potentially huge liability-related costs, even if they never lose a lawsuit. To take one example, a company named Vitek manufactured an estimated 26,000 jaw implants using about 5 cents of DuPont Teflon in each device. The device was developed, designed and marketed by Vitek, which was not related to DuPont. When those implants failed, Vitek declared bankruptcy, its founder fled to Switzerland, and the patients sued DuPont. DuPont's record in court so far has been enviable—258 wins and one loss—but the cost has been staggering. Aronoff estimated that DuPont alone was spending at least $8 million per year over the past 5 to 6 years to defend these suits. To put this in perspective, DuPont's estimated legal expenses in these cases for just 1 year would buy over a 13 year supply of DuPont's Dacron polyester, Teflon and Dalcrin for all U.S. makers of implantable medical devices.

Faced with this cost/benefit picture, DuPont decided, in January 1993, to stop selling its products to manufacturers of permanently implanted medical devices. At that time, DuPont said it would only permit manufacturers to purchase a year's supply, based on historical buying patterns. DuPont has subsequently allowed manufacturers to purchase up to three more years worth of raw materials.

One supplier's decision alone would not be troublesome except that there is no reason to believe that the economics will be different for other suppliers around the world. One of our witnesses today has already contacted 15 alternate suppliers of polyester yarn worldwide. All were interested in selling her raw materials—except for use in the United States.

What is at stake here? Without raw materials, you cannot make a final product. Take this heart valve, for example. Around the edge of this valve is a sleeve of polyester fabric. This fabric is what the surgeon sews through when he or she installs this valve. Without this valve, the patient will surely die.

Take another example, a pacemaker. Pacemakers are installed in patients whose hearts, because of heart attacks or for other reasons, no longer generate enough of an electrical pulse to get the heart to beat. To keep the heart beating, a pacemaker is installed on the left side of the chest. It is connected to the heart with wires. These wires have silicone rubber insulation. Unfortunately, the suppliers of the rubber have begun to withdraw from the market. Without this pacemaker and its leads, the patient will surely die. With that pacemaker, the patient can live for decades.

Take still a third example. We have in the room today a 9 year old boy who suffers from hydrocephalus, a condition in which fluid accumulates around the brain. Without a hydrocephalitic shunt, that boy's head would have expanded until he was killed. With that shunt, he has been able to live a normal life.

We will also hear today from a woman who has already "died" twice when her heart stopped beating. She was lucky enough to collapse in the midst of people who could sustain her with CPR until she was revived. Today, she lives an active, normal life. She has some assurance that she will not keel over dead at any moment because she has an implanted automatic defibrilator.

We cannot allow this woman, the 9 year old boy, the person with a pacemaker, and the patient with the heart valve to become casualties of our liability system. If the economics of supplying raw materials to the implantable medical device makers is as bad as it seems, it is imperative that we act. It is irrational and unfair to expect raw materials suppliers to continue to serve the medical device market as an act of charity, notwithstanding the liability-related costs. We need to rationalize our product liability laws in this area, to give raw material suppliers some assurance that unless there is real evidence that they were responsible for putting a defective device on the market, they cannot be sued simply in the hope that their deep pockets will fund settlements in lieu of spending money on litigation costs.

I have long believed that the fight for liability reform was as much a pro-consumer fight as it was a pro-business one. I believe that the testimony we will hear this morning proves this once again. When fear of liability suits and litigation costs drives valuable, life-saving products off the market because their makers cannot get raw materials, consumers cannot possibly come out ahead. When companies must divert money from developing new life-saving products to replacing old sources of raw materials supply, consumers cannot possibly be coming out ahead. When one company must spend millions just to defend itself in lawsuits over a product it did not design or make—for which it simply provided a raw material ingredient—consumers do not come out ahead. This morning's hearing dramatically illustrates that efforts to increase compensation for the injured can sometimes come at an unacceptably high cost to the rest of society.

We must find the right balance. We cannot tolerate a situation in which suppliers of some of our country's most sophisticated raw materials feel they must refuse to make those materials available to manufacturers of life-saving and life-enhancing medical devices simply to protect themselves against the cost of defending liability suits.

Based on the testimony we will hear this morning, I am committed to forging a solution that will head-off this threat to our national public health. This morning the Subcommittee is releasing a staff draft of possible legislation. While I do not expect our witnesses to be able to comment on this draft this morning, I plan to introduce a final bill shortly after the Memorial Day recess. It is my hope that Congress will act on this bill before the end of the year. The patient is in critical condition, and we need to perform emergency surgery. Delay could, quite literally, be deadly.

We have three panels of witnesses to assist us in exploring this problem this morning. The first panel consists of medical device manufacturers and raw materials suppliers. On the second panel are patients, physicians and medical researchers who will tell us what the current situation means for medical care. Our third panel is Ms. Kristen Rand, counsel for Consumers Union.

Senator LIEBERMAN. We have three panels of witnesses to assist us in exploring this problem this morning. They are a superb group of witnesses. I appreciate very much their willingness to be with us today, and I look forward to their testimony at this point.

Let me say to all the witnesses that in the cases, which are most of you, where you have submitted testimony for the record, we will include it in the full record of the hearing. We are going to run the lights here as a way to try to—we have 10 witnesses and a long hearing, and so we want to give everyone a fair chance to speak. The lights are going to run on a 5-minute cycle. I hope you can speak in that time. If you feel that there is something particularly important that you have not had a chance to say in the 5 minutes, do not feel that your First Amendment rights to petition to Congress are unduly restricted.

We will begin with Mr. Paul Citron, who is the Vice President, Science and Technology, of Medtronic, Incorporated, and we are going to hear on this panel from people who are in what I would call the medical device industry.

Mr. Citron, thanks for being here, and we look forward to your testimony now.

TESTIMONY OF PAUL CITRON,[1] VICE PRESIDENT, SCIENCE AND TECHNOLOGY, MEDTRONIC, INC.

Mr. CITRON. Thank you, Mr. Chairman. Among my responsibilities at Medtronic is assuring that our company is technologically positioned to develop and produce high-quality, innovative products that treat disorders of the circulatory and neurological systems.

Senator LIEBERMAN. Let me ask you to move the mike as close as you can, because it is very directional.

Mr. CITRON. Sure. Medtronic, by the way, is a leader in producing therapeutic medical devices to improve cardiovascular and neurological health of patients around the world.

It has only been 40 years since the first development of medical device technology which has allowed physicians to effectively replace body parts which have become damaged by disease. A progression of innovative therapeutic technologies has restored health to literally millions of patients around the world.

The brief history of medical device breakthroughs begins in the 1950's when large-diameter vascular grafts permitting the replacement of dangerously weakened major blood vessels were first developed. In 1958, the first electronic device, the cardiac pacemaker, was implanted in a patient. This revolutionary technology stimulated hearts that had too slow a heart rate—to a rate approximating normal. With this technology, the heart was once again able to pump sufficient quantities of blood to meet the majority of the patients' hemodynamic requirements. Without pacemakers, patients typically experience sharply limited ability to conduct daily living tasks, suffer from fainting episodes, and experience premature death.

The 1960's saw the emergence of the mechanical heart valve as a practicable replacement for defective natural valves. Implanted medical devices such as these offer therapy where previously none was available. In many instances, they offered patients the possibility of saving and enhancing their lives. Perhaps the clearest example of the life-saving capacity of medical devices has been the development of the implanted defibrillator that you alluded to a few moments ago. This emerging technology is capable of detecting dangerous heart rhythms which can lead to fibrillation—or detecting fibrillation itself—and automatically delivering a precise shock to the heart to restore normal rhythm. Carefully selected patients who receive such devices would have been likely victims of what is very aptly known as "sudden cardiac death syndrome." Instead, they have been able to lead longer, productive lives. But the increasing imposed unavailability of materials used to produce these critical technologies jeopardizes their availability.

It is important to note the hostile environment in which implanted medical devices must function. The body has created a formidable set of defenses against foreign materials. The body recognizes these materials as being potentially dangerous and vigorously sets out to consume, destroy, or isolate them. These defenses work

[1] The prepared statement of Paul Citron appears on page 45.

very well. Unfortunately, the body does not recognize medical devices as allies and seeks to destroy them as if they were deleterious rather than beneficial. Only a limited number of specialized materials such as certain polyurethanes, a small number of other polymers, solid silicone rubber, and an equally small number of inert metals and exotic alloys have been found, when used in properly designed devices, to be clinically acceptable for direct implantation and contact with tissue. These materials are used to construct the implant itself or serve as the protective barrier to shield other components which are not themselves clinically acceptable for implantation. Without such materials, therapeutic implants would not be possible.

As if the requirement of clinically acceptable tissue responses was not enough, implanted materials must also be biodurable. These are challenging requirements which are being met with today's technologies. Even though performance is excellent, there is, however, room for improvement. The perfect implant has yet to be developed. The industry must have access to new and better materials and components to continually advance performance and, in this way, improve health care.

The impact of medical devices has been profound and far reaching. A 1994 study shows over 5.5 million U.S. patients annually are affected by life-saving or life-enhancing medical device technology. In the cardiovascular arena alone, over 1.2 million procedures are performed each year to open blocked arteries with balloon angioplasty, restore heart rhythms with implanted pacemakers and defibrillators, provide respiratory and circulatory support during open-heart surgery, and repair blood vessels with synthetic grafts. This industry has global significance and is one of the few in which the United States has a positive trade balance. Current estimates are that the United States medical device industry will produce a $4.1 billion favorable trade balance on $40 billion of annual sales. The best measures of the effect of medical device technology, though, is in terms of how it improves and sustains patients' lives. We must never forget this.

In spite of the enormous contribution medical devices have made to the public health, the manufacturing of these products is a business that frightens many. This fear is largely a consequence of the possibility of liability exposure in the event a device malfunctions or fails. As with other business enterprises, the specter of product liability in medicine is peculiar to the United States. Its influence is growing and is having a chilling effect on innovation. Ironically, the shadow of product liability may actually be serving to keep better performing products from the market rather than being a force for improvement for the following reasons:

First, medical device manufacturers must rely on components and raw materials manufactured by other firms in order to produce their end-products. The majority of devices integrate a broad range of technologies. In many instances, these are components which are being produced for other commercial applications but have also been qualified by device manufacturers for use in medical applications. For example—and you spoke to this earlier—the mechanical heart valve has a sewing ring which allows the surgeon to attach the heart valve to the heart. This sewing ring is made out of a pol-

yester material, Dacron in this case, and that material has become unavailable to us.

To the best of our knowledge, there have been no clinically adverse events associated with a fabric or fiber, and yet, as I said, a key manufacturer of the fibers has notified the heart valve industry that it will actively discourage the use of its material in permanently implanted products. The company concluded that selling raw material could not be justified in light of the risk of litigation associated with having their raw material in these valves.

As other witnesses will testify to, raw material suppliers are named in product liability cases even when they had no direct involvement in the design, specification, or manufacturing of the product, simply because they are another possible source of compensation. Despite the fact that they are usually able to prevail on the merits, the cost of proving themselves not to be liable and the negative publicity they receive far outweighs any revenues they receive for the materials they supply.

As an illustration, the worldwide polyester yarn market is estimated to be over $9 billion in annual sales, while the implant market for these fibers for the entire medical device industry is less than $200,000 per year.

Senator LIEBERMAN. Let me just stop you there because I think the mathematics are so powerful. It is a $9 billion annual worldwide market for these fibers.

Mr. CITRON. That is correct.

Senator LIEBERMAN. And the part of the market that is related to the implantable devices is $200,000 a year.

Mr. CITRON. That is correct. So it is hardly noticed by the manufacturers of the fibers.

Analogous ratios exist for other polymeric materials and components. Sales to the device industry, therefore, are really inconsequential. On the other hand, the cost of defending against lawsuits runs into the millions of dollars.

Because of the growing proscription of materials and components for life-saving medical devices, the industry now is engaged in an all-out effort to find and qualify equivalent replacement materials and sources of supply. To the extent we are successful, the resources expended on these initiatives will merely get us back to where we were. We will not have advanced the State of the art. The flow of new materials which would permit as yet unmet clinical needs to be addressed will be markedly slowed. The exiting companies have the laboratories from which future breakthroughs would likely have occurred.

We face a real and imminent danger that high-quality life-saving and life-enhancing medical devices will become unavailable because critical materials and components are made unavailable. For patients, the consequences can be tragic. A remedy must be found which will provide the protection necessary to assure that suppliers will continue to provide materials to manufacturers. Unless such a remedy is put in place, we will experience inexorable declines in medical device innovation, quality, global competitiveness, and, most distressingly, the public health as certain patients are not able to obtain life-saving and life-enhancing technologies.

Thank you, Mr. Chairman.

Senator LIEBERMAN. Thank you, Mr. Citron. I will have some questions for you after we hear from the other witnesses, but I do want to just punctuate something you have said, which is obviously our main concern here is on public health and on the impact it would have on the lives of real people if these medical devices are not able to be manufactured because of the inability to acquire raw materials. There is another concern, however, and that is an economic concern or a jobs-related concern, which is that this medical device industry is a relatively strong industry in this country. It is a job creator. It is one of those industries in which we in the U.S. are the dominant worldwide factor, as you stressed with the number that we have a $4.1 billion trade surplus in this area. So what is on the line, first and foremost, is people's health, but what is also on the line are people's jobs.

Mr. CITRON. Without any question.

Senator LIEBERMAN. I thank you.

Let's go now to Ms. Eleanor Gackstatter, who is the president and chief operating officer of Meadox Medicals, Inc.

TESTIMONY OF ELEANOR GACKSTATTER,[1] PRESIDENT AND CHIEF OPERATING OFFICER, MEADOX MEDICALS, INC.

Ms. GACKSTATTER. Thank you, Mr. Chairman.

My name is Eleanor Gackstatter, and I am president and chief operating officer of Meadox Medicals, Inc., a medium-sized company that employs 600 people. Located in Oakland, New Jersey, Meadox has been privately owned and operated by William J. von Liebig since 1961.

I appreciate the opportunity to testify here today, Mr. Chairman, on an issue that threatens the future of dozens of medical device companies and the well-being of millions of patients the world over. I refer to the impending shortage of raw materials used in manufacturing many implantable medical devices. This is a major health care crisis, and time is quickly becoming the enemy for American surgeons in vascular, cardiothoracic, and general surgery—and, most importantly, the patients they serve.

Meadox Medicals was involved in the early days in development work using DuPont polyester yarns for implants, as bypasses for arteries. Since that time, our company has dedicated its efforts to being a specialty manufacturer of products for vascular and thoracic surgery. Through the years, polyester yarns have served this area of medicine well. Today, nearly 100 percent of Meadox's line of vascular grafts and fabrics are made of polyester yarns. Research and development for improved treatment and use of those yarns has been a major focus in our company and is closely aligned with the requests and demands of our company's customer base—the vascular, cardiothoracic, and general surgeons.

In late 1992, however, medical product manufacturers such as Meadox were given notice by their polyester yarn suppliers—in our case, DuPont—that by January 1993 all supplies of this material would be stopped. Why? Because raw materials suppliers no longer wish to confront the threat of litigation that can consume millions

[1] The prepared statement of Eleanor Gackstatter appears on page 47.

of dollars because of products that represent a very small part of their total business. This is the crux of the present crisis.

Meetings between Meadox and DuPont yielded agreement that a 3-year supply of DuPont Dacron polyester would be provided, based on Meadox's traditional usage of the material. We must have polyester or an acceptable substitute material in order to continue manufacturing vascular grafts and fabrics. Since the time of DuPont's notification, Meadox Medicals' efforts to find alternative supply sources have been exhaustive and expensive. Those efforts have also had a huge impact on the company's R&D resources.

In 1994, Meadox Medicals, Inc. has budgeted its R&D at double the industry average as a percentage of sales. A significant amount of those R&D moneys are dedicated to polyester yarn replacement. We are spending valuable time looking for alternatives to a material that has served the American public well for over 35 years. Resources are being taken away from the search for new and better utilization of yarns that would yield improved or innovative products.

As a company, survival comes before the future, but how can we measure the loss created in the future for American surgeons and their patients by our actions today? When supplies are vanishing, how can we choose to provide R&D supplies for future innovative products when the surgeon needs our products to save a life today?

If you consider the uses of the products Meadox makes, you can easily understand the importance of our company's commitment to this specialty: artificial blood vessels for replacing diseased arteries; fabrics for patching holes in the heart; cuffs for heart valves so that they can be sutured to the body, primarily with polyester sutures, very much as has been discussed prior; conduits or tubes so that valves can be placed inside of them; fabrics for repairing hernias; and, most critically, the vascular graft used to replace a ruptured artery in abdominal aortic aneurysms, or AAA's.

Aneurysms are the 13th leading cause of death in the United States, and the incidence is rising as the population ages.

Senator LIEBERMAN. Why don't you describe that in a little more detail and how your products respond to an aneurysm?

Ms. GACKSTATTER. One of the situations when you have an artery that ruptures, in this case this is one of the most drastic situations that can occur, because the time—50 percent of those that have this situation as an emergency never make it into the OR. And when they get there, there is a traumatic situation in the OR. An implant has to be put in very much like this. If the artery has burst, it is open. It is like a balloon, and it breaks open. There is a tremendous loss of blood. There is the importance of speedy surgery at that point with the surgeon knowing exactly what to do. He must get in there quickly. He must put this conduit in. He must be able to suture it. In some cases, we also have a product that allows him to do some tying without suturing and then get back into it later to prevent all that blood from being lost, and also the trauma that the patient is in. But he must put this in quickly.

At that particular time, there is no time for that surgeon to get into the person's body and replace it with something that the person has in another part of his anatomy. At that time, he has one

choice only, and that is to go to the shelf and to find a material that he can use as quickly as possible.

Mr. Chairman, our concern is that the day will come where that product will not be on the shelf.

The other part of aneurysms is that early screening is something we as a company also support, because if we can get to the part where there are no ruptures but actually get to the aneurysm and do the procedure in the OR, it is that much easier for us to address this issue, because you are not getting into an emergency situation and you are allowing earlier discovery on the part of the surgeon to treat the ailment.

We are finding that more and more screening of this nature is allowing us to see that aneurysms are larger than we have thought. As a matter of fact, screening for early detection of aneurysms has shown that more aneurysms of all sizes were diagnosed from 1971 to 1980 than in the previous 2 decades. The more that we are trying to find this screening and encourage people to go out and get a screening, we are finding that those numbers are rising.

Senator LIEBERMAN. This is a condition that occurs primarily in older people?

Ms. GACKSTATTER. Well, actually, it can occur at any time, but it does occur in 50-year-olds. That is primarily where a lot of the findings as far as ruptures are concerned, and the 70-year-olds are starting also to show higher incidence.

I think I would like at this time, if I could, just to take a passage from one of the articles that a doctor of ours has written, which goes to the health care reform issue about costs also.

Senator LIEBERMAN. Let me ask you to try to be as brief as you can.

Ms. GACKSTATTER. Yes, I will. "Aside from the cost in lives, ruptured aneurysms impose an increasingly onerous financial burden on hospitals. On the basis of cost reimbursement data for Diagnostic Related Groups, one study documented that emergency operations resulted in a mean financial loss to the hospital of $24,655 per patient. Another study estimated that 2,000 lives and $50 million could have been saved annually had aneurysms been treated before rupture."

As a leader in our segment of the medical device industry, Meadox Medicals is stepping forward today to inform the public of this supply problems because its major shareholder determined it was critical, and ethical, to do so. Companies who use even smaller amounts of these materials for component parts of medical devices may not have yet felt the crunch. But they soon will. This is an equally troublesome situation.

Meadox intends to keep working closely with its surgeon customers as it has through the years. Internal processing for the most efficient use of its supply of polyester yarn is a major focus. But if there is no immediate or interim solution to this availability issue, we must all be concerned with the gap being created—the gap between the time required to find alternative sources and the time required to do the testing to show equivalency to the present polyester yarn.

Once we do the testing of the alternate materials, the time required to win Government approval of those materials can make

the process prohibitive, not only for the small manufacturer but also for the larger manufacturer. If, in fact, DuPont has treated all manufacturers equally, then all implantable medical device manufacturers have only one-and-one-half years to overcome this crucial gap in time. Meadox has already contacted more than 15 alternate suppliers worldwide. They were all interested initially, and they are willing to offer supplies for worldwide distribution, except in the United States. Their reason is always the same: The risk of liability is too high for the size of the market.

Senator LIEBERMAN. That is very powerful. Let me just ask you to go over that again. You have literally sought out 15 different suppliers of raw materials for your products. Fifteen said they were interested in supplying you unless you were going to use it in the United States.

Ms. GACKSTATTER. Yes.

Senator LIEBERMAN. Because of the legal liability system.

Ms. GACKSTATTER. Yes. The size of our market is just too small, and particularly in our case, we are very specialized to our particular surgeon customers, and they just do not feel that the litigation that they would have to go through in supplying us would be worthwhile dealing with us.

They are perfectly willing to work with us overseas so we can distribute worldwide. You have to think about us possibly having to move our manufacturing—as a matter of fact, we did start some of our parts of our manufacturing in Europe, and we also see the possibility that—I mean, what this comes down to in the end is that you are looking at less jobs manufacturing this material in this country because you try to be close to your source.

Senator LIEBERMAN. The other thing that this says—I do not want to go on too long on this—just from your survey is that the legal liability system in the United States is dramatically different than the liability system that exists anywhere else in the world.

Ms. GACKSTATTER. Yes, that is correct.

Senator LIEBERMAN. So they would sell you these materials for use in your products if the products were going to be sold anywhere else in the world.

Ms. GACKSTATTER. Yes.

Senator LIEBERMAN. OK. Can you wrap up your testimony?

Ms. GACKSTATTER. Yes, surely. Well, I guess the thing I really want to emphasize is that we make life-saving products. If we cannot get the raw material, we are talking about patients losing lives. This is what we have dedicated our entire service to the surgeons to, and it is something that we feel—I guess even from an R&D standpoint, it shows that there is a time in which we cannot bring all our R&D facilities and the things that we would like to do for the future and new products in the future. So if we had been forced to have this level of concern of liability risk in the years we were developing things, I hate to think of how many people might not be alive today or how many would have had a poor quality of life because they would lack the products we did, in fact, develop.

Constant dedication to a very small but specialized area of medical care has been our company's pride and creed. Included in this are the work and relationships with our suppliers that have helped us forge ahead into previously undiscovered areas of innovation.

I would also like to note that from standards in getting raw material, I would encourage the ability to have access to more of standard type products because we are the ones that make these products implantable. It is not the items that we take off the shelf. If we cannot preserve that spirit of innovation today, then time may well be running out for American surgeons and their patients.

Thank you.

Senator LIEBERMAN. Thanks, Ms. Gackstatter. I appreciate that.

So now we have heard from two leading medical device manufacturers. Now we are going to hear from Katherine Know, who is the business program manager, Central Research and Development at DuPont Company, which has been referred to here as a major supplier of these products to the medical implant industry.

Ms. Knox, thanks for being here. We look forward to your testimony now.

TESTIMONY OF KATHERINE F. KNOX,[1] BUSINESS PROGRAM MANAGER, CORPORATE NEW BUSINESS DEVELOPMENT, DUPONT COMPANY

Ms. KNOX. Mr. Chairman, thank you very much for the opportunity to be here today. I am, indeed, a business program manager for the DuPont Company. For the last year I have been working coordinating implementation of our policy regarding use of materials in implantable medical devices.

DuPont is the Nation's largest and oldest diversified chemical company. We are nearing the 200th anniversary of our founding on the banks of the Brandywine in Delaware, and we feel that that longevity is a direct result of our expertise in science and technology, especially in materials innovation and development. DuPont has been a leading manufacturer of many advanced materials, including nylon, Dacron, Teflon, Lycra, Kevlar, Mylar, to name only a few.

These materials have found their way into literally tens of thousands of products: clothing that we wear, the beds we sleep in, cars that we ride in. It is safe to assume that DuPont materials have touched every person who is here today.

About 50 years ago, medical researchers began looking at some DuPont materials for use in devices that could save lives or enhance the quality of lives. Ultimately our materials found their way into applications such as vascular grafts, as we have heard about, pacemakers, catheters, and many other applications.

That brings us to why I am here this morning. First I would like to state that DuPont is not here to ask this committee or the Congress for any specific action. We are here because we want to assist your fact-finding efforts to understand what the issue of materials availability is all about, and we do appreciate your leadership in this very important area.

DuPont is not in the business of designing, manufacturing, or marketing medical implants. As background, in the 1950's, when it became apparent that our materials were being used in implantable medical devices, DuPont adopted a very conservative policy which allowed sales of raw materials for implants only to

[1] The prepared statement of Katherine F. Knox appears on page 48.

those medical researchers, device manufacturers, hospitals, and other customers who agreed to certain terms and conditions of sale. We informed customers that the DuPont materials were designed and manufactured for industrial and consumer markets, not specifically for use in implants or any devices that were to be implanted in the human body. DuPont also informed these customers that we were not an implant manufacturers and that we did not seek or obtain FDA approval of any medical devices made with our materials. We required the customers to sign a disclaimer saying that they would take responsibility for performing all of the tests that are necessary for using materials in implants and that they themselves would obtain all of the necessary FDA approvals.

We felt that this was a reasonable policy which would avoid slowing or stopping medical advances.

Senator LIEBERMAN. I presume most of this was because of the concern of the company at that point about the potential legal liability.

Ms. KNOX. Well, Mr. Chairman, I do not believe at that time that legal liability was that much of an issue. It was just simply that the materials were designed and manufactured for industrial and consumer uses, not designed and manufactured for implants. We understood that the implant market is a market that requires very, very specialized testing, very rigorous testing. We did not do that kind of testing ourselves, and we felt comfortable that the customers that we sold the materials to who signed disclaimers would assume that responsibility themselves.

Senator LIEBERMAN. OK.

Ms. KNOX. But it was primarily because the materials are not medical-grade materials.

We relied for many years on our customers, the medical experts, and the FDA to review the safety and efficacy of the medical devices. However, changes in business and legal trends occurred and made it necessary for DuPont to adopt our current policy. As of January 15, 1993, DuPont no longer supplies material to firms using these materials in permanently implantable medical devices, unless DuPont is involved in the design of the device itself.

Senator LIEBERMAN. So that there is an exception, that if you are involved in the design of the device, you are willing to supply materials. Is that correct?

Ms. KNOX. Yes, that is correct, and I have a specific example of that. We have a joint venture called DePuy–DuPont Orthopedics, where we participate in a joint venture situation with DePuy in designing and manufacturing materials for orthopedic implants.

Senator LIEBERMAN. OK.

Ms. KNOX. But that is a situation where DuPont is in the device business itself.

Senator LIEBERMAN. Right, and, therefore, feel it is appropriate to assume responsibility because it is not just that you are selling a raw material. You are actually making—you are participating in the manufacture of the product.

Ms. KNOX. That is correct. Our role is as the manufacturer of the finished product, not simply as the manufacturer of the raw material.

Once we announced our policy, we honored our customer-supplier relationships for 1 year until January 31, 1994, to allow our customers time to locate alternate suppliers or alternate materials. We additionally gave all of our customers the names of our competitors in this area so that they would have a place to start their search for alternate materials.

We understand that the medical devices that our products are used in provide very high value to patients and are important life-saving or life-enhancing products. But, unfortunately, as you indicated and as the other witnesses have indicated, in America very often disappointment in medical treatment can result in lawsuits against any company that is even remotely connected with the medical product.

In recent years, there has been a growing trend to sue raw material suppliers, even though they have not been involved with the design, the testing, or the manufacture of the device.

Generally the courts have found that raw material suppliers are not responsible for liabilities created by finished medical implants. Mr. Chairman, as you mentioned yourself, in the case with the Vitek lawsuits we have a tremendously successful record of 258 cases where we have been found by the courts to not be responsible for the liability created by the medical implants. However, as you know also, the cost of defending these cases successfully is very expensive. It is very enormous. Litigation can involve hundreds or thousands of cases and thousands of dollars per case, in document production, in discovery, and in lawyers' fees. This can translate into millions of dollars in defense costs even when the company is only the raw material supplier.

In almost all cases, the quantity of raw materials used to make a medical implant is minuscule. A few grams' or a few cents' worth of raw material goes into most medical implants. Therefore, $50 worth of raw material can make a thousand implants. Those thousand implants can generate 1,000 lawsuits. Those lawsuits can generate millions of dollars in legal costs even if the company is found to be faultless.

DuPont is a company that stands behind our products that we manufacture and sell. However, we generally do not manufacture and sell medical implants. A company whose only involvement with an implant is selling raw materials cannot justify to our investors, to our employees, and to our other constituencies the millions of dollars in costs, court appearances, and the press coverage that often can accompany controversies over medical implants.

The medical community has tremendous value for the thousands of useful modern implants. However, society has not always kept these benefits in mind when allocating responsibilities for the risks involved.

We feel that the litigation environment with respect to medical implants has become increasingly hostile to raw material suppliers. The medical community many not always have the deciding vote on highly publicized medical implant cases. The fact that the FDA approved the medical implant and frequently a majority of the medical community supported use of the implant may carry little weight with courts, the public, and the press. Companies associated with

the medical implant may become the object of endless lawsuits, negative press coverage, and public disapproval.

A company whose only involvement with the implant is selling raw materials cannot justify involvement in this area.

In summary, Mr. Chairman, we at DuPont are saddened by the need to withhold our materials from use in permanent medical implants. This was not a decision that we arrived at lightly. Since the decision was announced, we allowed a transition period. We reached out to our customers, even though this meant assuming additional risk, to be sure that we were acting responsibly in giving them time to find alternate suppliers or alternate materials. Unfortunately, the realities of the American litigation system no longer permit companies such as DuPont to supply small amounts of highly valued materials for use in implants without risking involvement in large-scale implant litigation.

Mr. Chairman, I would like to thank you for the opportunity to be here today, and I would also like to thank you for your leadership in this very important area.

Senator LIEBERMAN. Thank you very much, Ms. Knox. Is it fair to say—maybe I should ask Mr. Benson—that the decision of DuPont is typical of raw material suppliers generally in this area?

Ms. KNOX. Mr. Chairman, our action was a unilateral action, taken only because it made sense to the company. I would like to let Mr. Benson answer that.

Senator LIEBERMAN. Fine. Let me ask you to—James Benson is vice president, technology and regulatory affairs, of the Health Industry Manufacturers Association. Perhaps you will cover this in your testimony, Mr. Benson. If not, maybe you would just address briefly whether—am I correct that DuPont is the largest supplier of raw materials in this area?

Mr. BENSON. I believe DuPont is the largest supplier. We are aware of two other major suppliers that have made similar announcements. Dow Chemical, Dow Corning, and DuPont are the three major ones. I have also seen a letter from Shell saying that they are also cutting back or stopping supplying materials. So that is actually four major companies that we are aware of that have made this decision.

Senator LIEBERMAN. Let me, while I am on this track, just ask you, Ms. Knox: Another alternative here presumably would be to substantially raise the price of the raw materials that you are supplying to try to protect yourself, to cover the risk of the lawsuits that you are afraid might come. Was that considered, or is the cost so disproportionate to the legal exposure here that it doesn't work in the marketplace?

Ms. KNOX. Mr. Chairman, you are absolutely correct. The cost really is disproportionate. We understand that there are over 20,000 medical device companies in the world. If each one of those companies had only 10 products—and I know that companies like Meadox and Medtronic have many, many more than 10 products each. But even if each company only had 10 products, that could be right there 200,000 products. Each one of those products could have hundreds or thousands of lawsuits associated with each one. So it is almost an endless possibility of lawsuits associated with

using these small amounts of material—it really is not something that could be covered as a price issue.

Senator LIEBERMAN. OK. Thank you.

Mr. Benson?

TESTIMONY OF JAMES S. BENSON,[1] SENIOR VICE PRESIDENT, TECHNOLOGY AND REGULATORY AFFAIRS, HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

Mr. BENSON. Thank you, Mr. Chairman.

As you pointed out, I am representing the Health Industry Manufacturers Association, and that organization represents more than 700 manufacturers of medical devices, diagnostic products, and health care information systems.

I appreciate the opportunity to testify here today, Mr. Chairman, on a subject that is, as you have already heard, of grave concern to our Nation's health; that is, the impending shortage of raw materials that medical device manufacturers use to produce devices for implantation within the human body. This issue is especially critical for many small device companies.

The medical device industry is extremely grateful to you for holding this hearing so that this problem can be brought before the Subcommittee, the Congress, and the American people.

Basically, the problem is this: As a direct result of the liability environment in this country, three major raw material suppliers recently announced that they would limit or cease altogether their shipments to medical device manufacturers. Those are the three that I mentioned that you asked about earlier, and I would add Shell to that group as well.

You have already heard why the suppliers acted as they did and about the impact of these decisions on some medical device companies. There are those, Mr. Chairman, who might argue that suppliers ought to be held liable if a manufactured product using their materials causes an injury. But suppose a car wrecks because its steering mechanism fails. Should the supplier who provided the steel for that car be held accountable if the steel meets company specifications and the failure is the result of faulty design or manufacturing by the car company?

Senator LIEBERMAN. That is a very powerful point, and I hope you will just expand that a little bit here. Obviously we are not trying to protect anybody from a lawsuit based on a deficient product that, in fact, caused injury to somebody's health. And your analogy is a brilliant one, I think, which is that if the car is defective, why give the plaintiff the right to sue the steel manufacturer if the steel was up to the manufacturer's specifications. Obviously the suit should be against the automobile manufacturer.

Mr. BENSON. Exactly the point.

Senator LIEBERMAN. And the same here, the suit, if it is appropriate, should be against the medical device manufacturer, not against the raw material supplier.

Mr. BENSON. That is exactly right. I think it speaks very well of this industry that the device manufacturers are very willing to step forward and take that responsibility. All they ask is that the mate-

[1] The prepared statement of James S. Benson appears on page 51.

rials be manufactured according to whatever agreements have been made.

Shouldn't the supplier's responsibility to defend lawsuits then be limited to where its own wrongdoing led to the injury?

Before I discuss the history of the biomaterials availability problem and offer a suggested solution, let me say a word about the medical device industry itself. First of all, device companies are innovative. More than two-thirds are small entrepreneurial companies. The fruits of their extensive investment in R&D are products that enhance the quality and value of patient care and increase the productivity of the U.S. health care system. Just think of the marvelous medical technologies that have been made available to us over the last 20 years, from new diagnostic imaging devices and implanted defibrillators, to lasers for intricate surgery. Many of these breakthrough devices were developed by small companies.

Innovation by U.S. medical device manufacturers has made the U.S. industry the world leader, with a positive balance of trade in excess of $4 billion, as has already been pointed out. But our industry's global competitiveness is clearly at risk without a steady supply of raw materials.

Our concerns about the effects of the biomaterials shortage are confirmed in a market study conducted by Aronoff Associates. Subcommittee members have received a copy of this report. The Aronoff study focused on three very common materials that have been withdrawn by DuPont from the permanent medical implant market.

The study found that the combined size of the permanent medical implant markets for these three materials alone is $600,000 a year, compared with the total markets for these three materials of $10.5 billion, roughly a ratio of 1,000 to 1.

In many cases, there are no alternative suppliers for these materials. Where alternative suppliers exist, those willing to consider supplying will insist on financially stringent indemnification agreements covering as much as $1 billion. This would clearly put such agreements out of reach for small companies, the engines of innovation in the medical technology industry.

Unfortunately, for many materials, suitable replacements simply do not exist now, and Aronoff Associates offers some startling forecasts. Over the short term, 1 to 3 years, the financial requirements needed to back indemnification agreements will begin to force small manufacturers and start-ups out of business. Some materials will not be available at all. U.S. manufacturers will have to divert resources from R&D to search for and qualify replacement materials. This is already happening for many companies, as you have heard today.

Assuming manufacturers' reserves of the DuPont materials do not deteriorate, a DuPont material shortage will not be felt by patients in the immediate future. However, they will feel the shortage in the long term. Over the next 3 to 10 years, Aronoff estimates, the full effect of the biomaterials crisis will be felt unless substitute materials are found and approved for marketing. This means, quite simply, that patients will not have access to life-saving, life-enhancing medical implants if suitable replacements are not avail-

able. All together, more than 8 million patients every year could be affected, and I believe that is a very conservative estimate.

In conclusion, Mr. Chairman, HIMA believes that the only way to avert a biomaterials crisis is timely legislation that limits supplier liability to instances of genuine fault. That legislation should also establish a procedure ensuring that raw material suppliers will not be brought into litigation unless there is good reason to believe they are, in fact, at fault.

The impact of this approach will be that manufacturers ordinarily appear in lawsuits on behalf of suppliers, thus relieving the suppliers of heavy legal defense costs. Device manufacturers are willing to assume this burden as a way to help ensure the continued availability of the materials they need to make their products—products that American patients so desperately need.

HIMA appreciates your interest in this matter, Mr. Chairman, and we would be happy to work with the Subcommittee in any way we can to find a suitable solution.

Senator LIEBERMAN. Thank you, Mr. Benson. Let me just clarify what you said at the end. Did you say that the medical device manufacturers are prepared to assume the litigation costs for the raw material suppliers as a way to try to keep them in the market?

Mr. BENSON. I think this is the point that I was trying to make earlier. Yes, the device manufacturers are willing to take that full responsibility as long as the products, the raw materials that they have gotten simply come up to the standards that have been agreed upon, published standards or whatever is appropriate.

Senator LIEBERMAN. All right.

Ms. Knox, I do not know whether you are able to answer it now, but is that not sufficient, that promise of the medical device manufacturers to assume litigation costs for suppliers like DuPont? Is that not sufficient to keep DuPont supplying those raw materials?

Ms. KNOX. Mr. Chairman, we considered the possibility of using indemnification as a form of risk management, and we felt for the situation involving permanent implants that that is not really adequate risk management because it can be very problematic in the long run. We do accept indemnification as a form of risk management for use of our materials in certain circumstances where the device is only temporarily implanted.

Senator LIEBERMAN. Let me try to draw you out a little bit on that. The difference is that this is a permanently implanted device, and is your concern about the long-term impact on the person who has the device, or are you concerned about the long-term viability of the manufacturer? In other words, will the manufacturer be around to pick up the litigation costs?

Ms. KNOX. Well, primarily we are concerned about the fact that the situation involving permanently implantable devices is one where we consider the risk to be astronomical, where there is almost an unlimited number of lawsuits possible based on the large number of medical device manufacturers and the large number of products that they provide. So we just feel that the risk is exceedingly high and out of proportion to volume of material that is sold into this area.

Senator LIEBERMAN. And, again, that is the point that the market here—that is, the money to be made—and I do not say that de-

rogatorily—is so out of relationship with the potential exposure that over a longer period even this indemnification is not enough to keep you in the marketplace.

Ms. KNOX. Correct.

Senator LIEBERMAN. Let me ask Mr. Citron and Ms. Gackstatter to talk a little bit more about what you are trying to do to find alternate supplies. For instance, won't you have the same problem with whoever develops an alternate to the polyester fabric that you are using around the heart valve? Are you thinking of trying to develop something that you can make yourself and, therefore, assume—in other words, you will become your own supplier?

Mr. CITRON. Well, let me address the latter part of the question first. We have looked at and considered self-supply, but, quite candidly, we use literally hundreds, if not thousands, of raw materials in our product lines. The quantities of these materials that we use are—in mass basis and weight basis very—very small. Many of these materials, even if we were to have the know-how and were to secure the licenses to be permitted to manufacture them, could not be efficiently manufactured in the very small quantities we need. Nor do we believe we could maintain the quality that is needed for these products. It is not a matter of just making a pound or two and making it of high quality. The notion of self-supply is thoroughly impracticable. So by and large, that is not an option.

What we are doing, as other witnesses have said, is scouring the world for alternate sources. Some of these materials are proprietary to only one company, however.

Senator LIEBERMAN. Right.

Mr. CITRON. So we need to find a substitute rather than an alternative, and somebody spoke to the exhaustive testing and qualification and time required to accomplish that.

Then I believe to the final part of your question, we are at risk that any of our suppliers can decide at any moment that the risk is too great for them to continue supplying us. Indeed, we have had other companies besides the four mentioned who have determined that they just do not feel that their risks warrant participation. They have announced their exit as well.

So the issue is that at any point in time we are vulnerable to having one or more additional suppliers decide to exit.

Senator LIEBERMAN. Ms. Gackstatter, talk a little bit about what your R&D is focused on, and see if you can answer for me the question about even if you come up with an alternative product, why won't the manufacturer of that material have the same dilemma that DuPont and the other suppliers have now?

Ms. GACKSTATTER. Well, that is just the critical issue, Mr. Chairman. We did consider also self-supply. We went back—I mean, that is very expensive for us. We are a smaller company. But we considered that, and we found that there is also a domino effect here. That is, even if we decided to go back and make the yarns ourselves, the raw supplier that actually supplies the resin that helps treat the yarn is now asking us questions about whether or not this would be used in medical devices. So the chain is going back further and further into the line, which to us is a critical issue.

So if we took the fact that we even had any opportunity as to availability, from an R&D standpoint one must consider again the

time for us to go through that development stage, if we do find it, go through the development of finding—you know, developing the raw material, going through our own process of making it implantable, that time will be passed the time that we have a supply from DuPont right now. And that is too late.

Many things will be happening to the patient at the time. I think that is the crux of what we are facing right now.

Senator LIEBERMAN. OK. I hear you.

If I remember correctly, in your testimony you talked about a 1½ year period, and then after that we will be at the crisis stage.

Mr. Benson, I think the Aronoff study talked about 3 to 10 years. Could you relate those two numbers?

Mr. BENSON. Yes, I would be delighted to. Aronoff Associates concluded that there would be short-term, long-term impacts. The short-term impact had to do with the loss of innovation, the fact that companies already were getting out of the business, the start-ups were not starting, the innovative process was going to be lost.

The long-term impact had to do with—at the time the study was conducted, which is now about a half-year ago or so, said that in the period from 1 to 3 years there were enough materials stockpiled that there would not be impact on patients. So during that early stage, you have companies losing the innovative edge because new ones are not coming, start-ups are not happening. The long-term impact would be on patients and would start about 2 years from now, which syncs with Ms. Gackstatter's 1½ to 3 years.

Ms. GACKSTATTER. If I can just clarify another point?

Senator LIEBERMAN. Go ahead.

Ms. GACKSTATTER. The situation within the 3-year supply is that in some yarns there are maybe slightly more usage than others, and the time that we had notification there was some imbalance. So during the time we got the supply for the 3-year cycle, we were already supplying into the back order situation. So that does not, you know, come out evenly within the 3 years. So that brings the product out of sync.

Senator LIEBERMAN. I understand and I appreciate that clarification.

A final question, if I can, to Ms. Knox. I am just wondering whether these twin problems that we have talked about of a relatively small market and high potential legal liability costs have taken DuPont out of any other non-medical markets.

Ms. KNOX. Mr. Chairman, the medical implant market is the only market where we have a corporate policy. However, we have on occasion in the past declined to pursue certain other opportunities because of the potential for very high liability. An example of that is about 10 years ago we had an opportunity to do some work with one of our customers into the possibility of manufacturing seismic bearings. Seismic bearings are used in construction of buildings such as houses, schools, apartment complexes, hospitals in areas that are prone to earthquakes, such as areas in California.

At that time, we evaluated that opportunity and considered that there was a very high potential for liability in that situation also, so we declined to participate in that area.

Senator LIEBERMAN. But other than that, this is unique because of the combination of these problems?

Ms. KNOX. Yes, that is correct. This is somewhat unique.

Senator LIEBERMAN. I want to thank the four of you.

Did you want to add something, Mr. Benson?

Mr. BENSON. Yes, I wanted to go back to your question of a minute ago. I think there is another point that is important to get on the record, and that is that the R&D energy that goes into searching for new products has a couple of negative sides. One negative side is that that is a loss of innovation right there, innovation that is going to be moving overseas, which is going to disadvantage this country both economically and from a health standpoint.

Senator LIEBERMAN. Right.

Mr. BENSON. We have had terrific products over the past 10 years. Just think of that accelerating technology evolution, that is going to stop.

There is another piece to this that I think is also important, and that is that materials like the DuPont materials are tried and true. We know what the experience with those is. As substitute materials come in, if they come in at all, we will not have that two or three decades' worth of history, and we will have lost that. And so we will be moving into a much more fragile situation. So there is a whole trend there that is moving this way, and it includes electronics, things like batteries for defibrillators and pacemakers. So that trend has just got to be stopped.

Thank you.

Senator LIEBERMAN. Thank you. I thank the four of you for your testimony. It has been very helpful, and I promise you that I am going to do everything I can to try to present a legislative solution to the problem. I always prefer a non-legislative solution, but as I listen to your testimony, I do not see a way to keep these medical devices on which we rely for the quality of our lives, indeed for our lives, without changing the rules of the game, which have just become unfair and gone out of control.

So I thank you very much.

Mr. CITRON. Thank you.

Mr. BENSON. Thank you.

Senator LIEBERMAN. I would call the second panel now: Mark Reily of Houston, Texas; Peggy Phillips of Falls Church, Virginia; Dr. J. Donald Hill, Chair of the Department of Cardiovascular Surgery at California Pacific Medical Center; Dr. Bernard Stulberg, Cleveland Center for Joint Reconstruction; and Dr. Pierre Galletti, University Professor and Professor of Medical Science at Brown University.

These obviously are folks who are either in the medical profession and using some of the products we have described or direct users—that is to say, people who are beneficiaries of these devices.

I want to thank you all. Some of you came from some distance. I know this is of real concern to you in a very personal way, and I appreciate the time that you are taking.

In introducing Mark Reily, I want to note for the record, as a parent of 4 children, how impressed I am by the patience and behavior of Thomas Reily in the midst of this fairly unentertaining morning, I would say.

Mr. REILY. Bribery is very effective.

Senator LIEBERMAN. Pardon?

Mr. REILY. Bribery can be very effective. [Laughter.]

Senator LIEBERMAN. I know the process. I want to hasten to say, not in my legislative life. [Laughter.]

Senator LIEBERMAN. In my parental life.

Mr. Reily, thanks very much for being here, and, Tom, thank you. We look forward to your testimony now.

TESTIMONY OF MARK REILY,[1] HOUSTON, TX

Mr. REILY. Good morning, Mr. Chairman. My name is Mark Reily. I am a joined by Thomas, my 9-year-old son, who is the reason I am here today. Together with my wife, Jane, and three other children, we live in Houston, Texas. I am here to highlight from Thomas' perspective, as well as my own, how recent events which have prompted the need for this hearing could collectively result in an unacceptable situation that will destroy thousands of lives of those who are dependent on implanted medical devices in order to live. Thomas is one of those people.

When Thomas was 8 months old, in October of 1985, he was diagnosed as having hydrocephalus, or "water on the brain." The so-called water of hydrocephalus is actually cerebrospinal fluid, a liquid produced in the brain that cushions it and the spinal cord. In hydrocephalus, the pint of fluid produced daily does not drain properly from the brain, thus accumulating abnormally in the head. The fluid builds pressure inside the head, like steam building inside a locked pressure cooker. If left untreated, it is a well-documented medical fact that the patient will initially suffer severe brain damage, become comatose, and ultimately die.

Fortunately, a procedure has been developed and refined over several decades that can alleviate this condition. A shunt tube made of a soft and pliable plastic material called silastic can be implanted in the brain and drained in the abdomen to relieve the fluid build-up. Through a combination of improved surgical procedures, the availability of the finest appropriate biomaterials for the shunts, and technology such as MRI and CT scan equipment for diagnosis, the outlook for the hydrocephalic patient has greatly improved over the last decade. However, it is critical to note that these patients, primarily children, will require a shunt for their entire life. There is no cure for hydrocephalus. Further, each patient will inevitably require shunt revisions on a periodic basis since, despite the advances cited earlier, the shunt may malfunction due to clogging, infection, or the child-patient outgrowing the tube's length. Thomas has had two shunt revisions since his original shunt was put in. Each year in the United States, there are approximately 75,000 shunt implant and revision procedures performed.

Jane and I will never forget the Saturday in late October 1985 that we learned that Thomas had hydrocephalus. We initially were told that based on the level of fluid accumulated on his brain and the resulting pressure, he would surely have brain damage, probably severe. Surgery to place a shunt in Thomas was scheduled for the first thing Monday morning. The hours from late Saturday to

[1] The prepared statement of Mark Reily appears on page 135.

Monday morning were the longest and darkest we have ever experienced.

The thought of needing to wait even 1 day to have the surgery was almost unbearable, for each minute that passed the pressure was building in Thomas' head, which could further damage him. Finally, the time came to drive to the hospital, and this act in itself lifted our spirits, for we were beginning to take action that would help Thomas. Modern medical technology would give Thomas a chance, and even in our moment of despair, this fact was not lost on us.

On Monday morning, Thomas received a shunt. Within hours, he was showing improvement. His lethargy disappeared. He was alert. He smiled again for the first time in weeks, and even stood up in his hospital crib. Within 36 hours, we were back home with the new Thomas. How different the outcome would have been for Thomas that day without the availability of the medical device he so desperately needed.

In the months that followed, we began adjusting to Thomas' condition emotionally. It is not easy to accept the fact that your child needs such a device as a shunt to live. But over the years, we have come to accept that fact and to be grateful for it. It is a cruel irony that as we have come to be at peace with his dependence on his shunt there are events transpiring that would make his life-saving device unattainable.

Six months after his original surgery, Thomas' shunt clogged and required revision. In the 6 hours that Thomas waited for his shunt revision surgery, he became violently ill, vomiting continuously and finally becoming semi-comatose. Mercifully, his revision was successful and immediately he regained his old form, laughing and smiling while playing games in his hospital bed. Again, how different yet predictably sad and final would have been Thomas' fate without this medical device.

Thomas went 6 years before his next revision was required, in 1992. But the scenario was the same. As the shunt malfunctioned, Thomas' condition deteriorated rapidly and relentlessly. When a new, properly functioning shunt was implanted, Thomas returned to his normal activities, working hard to overcome his learning difficulties, growing and maturing, and in a child's way striving to become a productive member of our society.

We had previously come to regard these shunt revision episodes as temporary mechanical digressions, sidelining Thomas for a week or so. If the lack of availability of required biomaterials for Thomas' shunt becomes a reality, as it appears it might, for Thomas these episodes will instead become a nightmare, with predictable, permanent, devastating results.

As I reflect on Thomas' brief life, I see a child who has already overcome a lifetime of medical difficulties. For in addition to the shunt implant and revision episodes I have detailed, Thomas was left with physical weaknesses from his hydrocephalus, requiring extensive therapy. When Thomas was 6, he was diagnosed with a very rare seizure disorder called Landau-Klefner syndrome, which left him unable to talk for over 1 year. But Thomas has endured and even prospered at times in the face of all these obstacles.

Early on, Thomas' mother and I went through a grieving process. We were grieving for the death of our vision of our perfect child. It was not until we left that vision go that we were able to see something much more beautiful: a young boy with an indomitable yet loving spirit who will not let his personal medical setbacks defeat him. I think that that must surely be God's spirit living inside him.

So I stand before you today, as the guardian of that spirit, as Thomas' father, beseeching you to do everything in your power to ensure that the biomaterials necessary for Thomas' medical implant device be readily available and of the highest quality. For some time in the future, perhaps next month or next year, Thomas will wake me in the middle of the night to tell me that his head hurts and that he thinks his shunt has broken. He will ask if we can go to the hospital to get a new one right away. I pray that I will be able to give him the only acceptable answer.

Thank you.

Senator LIEBERMAN. Thank you, Mr. Reily. I cannot thank you enough for your courage and grace in coming forward and telling this story. I agree with you. These are miraculous devices, miraculous events. This is really God's spirit at work here. We take this for granted, but when you think about the way our lives would be so much less without this help that the medical profession has been able to give us lately, we have got a lot to be thankful for. And obviously part of it is the spirit with which families like yours go at this. So I have tremendous admiration for you, and I appreciate very much your willingness to come forward, because it helps us make the case that there is something very important, which is the quality of people's lives, quality of children's lives at stake here, and that the legal liability system has gone out of control. A system that was based on some reasonable and noble purposes has gone to extremes which now turn it back on families like yours.

I just cannot thank you enough for coming forward. I wish you the best.

We are going to hear now from Peggy Phillips of Falls Church, Virginia. Thanks very much for coming.

TESTIMONY OF PEGGY A. PHILLIPS,[1] FALLS CHURCH, VA

Ms. PHILLIPS. Mr. Chairman, my name is Peggy Phillips. I am grateful for having the opportunity to appear before you today——

Senator LIEBERMAN. Ms. Phillips, try to pull that mike as close as you can. Thanks.

Ms. PHILLIPS. Is that better?

Senator LIEBERMAN. Yes.

Ms. PHILLIPS. —and share with you how a medical device known as an Automatic Implantable Cardioverter Defibrillator (AICD) has impacted my life.

The AICD monitors the heart and resuscitates you when you experience sudden cardiac death.

November 16, 1986, started off as a normal day. At the time, normal for me was getting up about 5:30 a.m., working all day as Chief of Congressional Affairs for the Air Force Surgeon General,

[1] The prepared statement of Peggy A. Phillips appears on page 136.

going to law school in the evening, getting home about 10:00 p.m. and working until midnight or so on office work or school work. I was used to the pace because I also went to undergraduate school in the evening while working full-time on Capitol Hill. I am sure this is similar to the schedule of a United States Senator.

However, on November 26, 1986, my life changed. I am told I collapsed as I walked from my office to my car. I stopped breathing. I had no pulse. I had no blood flow to my brain. I was clinically dead.

Fortunately, my car was parked next to a fire house, and I immediately received CPR from the paramedics. I was shocked back to life with a portable defibrillator and taken to a nearby hospital.

This experience was very difficult to adjust to. I have been very healthy all my life. In fact, November 26, 1986, was only the second time in my life that I was a patient in a hospital. The first time was the day I was born.

Medical personnel performed numerous tests in an attempt to find something wrong with me. They found nothing. I was diagnosed as experiencing sudden death syndrome and sent home on medications.

But, life was not the same. I felt fine, but my family and friends treated me like a piece of fine crystal. I tried to understand what they were going through. After all, I did not remember how I looked with the tubes in my throat and nose. I did not remember the needles in my hands and my arms. I did not remember being tied to the bed when I tried to escape from the hospital to go study for my law school exams.

However, I was determined to get back to my old routine. Then on the morning of December 15, 1986, less than 3 weeks after my first episode of sudden cardiac death, I experienced a slight chest pain while sitting up in bed. As luck would have it, my mother was across the hall and immediately responded to my faint call. As she entered the room, my eyes rolled back and my head slumped. I had died a second time. Mom began CPR and called the Fairfax County Fire Station #18 Advanced Life Support Emergency Team.

I wish my mother could be here today, Mr. Chairman. She is a very special lady and very determined. It is not often that a woman saves the life of the child she brought into this world. We should all have her strength. If anyone could convince you of the importance of finding some way of sheltering major corporations who make raw materials so others can advance medical science, she could.

The Advanced Life Support Emergency Team shocked me back to life and took me to a local hospital. More tests were conducted, but no cause for these sudden death episodes could be found. The doctors were hesitant to discharge me from the hospital. However, I was determined to get out of there and spend Christmas at home with my family. So I reluctantly agreed to have an Automatic Implantable Cardioverter Defibrillator implanted in my stomach.

Following a few minor adjustments, life with the AICD has not been much different than life before the AICD. In preparing for this hearing, I wrote down the positive and negative changes in my life since the surgery.

The negatives are somewhat silly: I had to get rid of 10 bikinis and 7 pair of skin-tight jeans. You know, the kind you have to lie down on the bed to zip up.

In addition, it took a while to get used to the scars, and I was self-conscious about the defibrillator showing when I wore certain clothes, like a swimsuit.

Finally, it is inconvenient having to have the battery checked every 2 months and undergoing surgery every 3 to 5 years to have the battery replaced.

The positive changes since my surgery far outweigh the negatives: I am able to enjoy life without my family and friends worrying that I am going to die again. I have completed my law degree and am now a member of three bars including the District of Columbia Court of Appeals.

I am an active member of the Board of Directors of the Washington Civic Symphony.

I try to exercise at least 5 days a week, including step aerobics, jogging, and weights.

I especially enjoy running up the 120 or so steps on the west front of the U.S. Capitol building, and I have run in 5K races.

I have been a part of the initial response team following some of the most devastating disasters in the history of the United States, including Hurricane Andrew and the Los Angeles riots. I was able to travel to these devastated areas without concern of an electronic malfunction, thanks to the AICD.

I know that I am lucky to be here today, Mr. Chairman. I was fortunate on November 26, 1986, when that Air Force sergeant brought me back to life. He later told me that I was his first save out of 10 victims.

I was fortunate on December 15, 1986, that my mother was across the hall. If she had been downstairs attending to my sister who was recovering from major back surgery, she would not have heard my call.

I was fortunate that the Fairfax County Fire Station #18 Advance Life Support Emergency Team brought me back to life.

I was fortunate that doctors like Levi Watkins, Dean, Postdoctoral Programs, Professor of Cardiac Surgery and Michel Mirowski, Professor of Medicine, The Johns Hopkins University School of Medicine, were persistent in developing the AICD, even though they were criticized by their peers.

I was fortunate that there are companies like DuPont, Dow Chemical, and others that develop new raw materials used to advance medical science, and companies like Cardiac Pacemakers, Inc. that manufactured the device in me.

Yes, Mr. Chairman, I know I am lucky to be here today. But what happened to me could happen to you or your loved one. Remember, I had no medical problems. There was no history of heart problems in my family. I was a good candidate not to have a cardiac arrest. But, it happened to me, and to this day, no one knows why.

Yet, the reason does not seem important now as long as I have the AICD. But I am concerned how much longer I will have that luxury when top suppliers of raw materials used in these devices are pulling out of the business.

As you can see, I am not a senior citizen. I hope to live another 50 or 60 years.

I have thought about how my life would be without the AICD. I think it would be similar to being in prison the rest of my life. And, Mr. Chairman, I do not know if I could handle that.

I consider what happened to me very personal, and I do not like to discuss it among strangers. I was told that I was one of the youngest patients to have an AICD implanted in this area. I am afraid that if people knew what I went through, they would treat me differently, probably the way I was treated after my first episode of sudden death, like a piece of fine crystal. While I enjoy fine crystal, I would prefer to be compared to a tough diamond.

For these reasons, it was difficult to appear before you today. However, I feel very strongly about the need to examine the liability concerns of raw material suppliers.

I am sure you have heard some horror stories of patients reacting to particular raw materials, or medical devices that do not operate properly. When I worked for the Air Force Surgeon General, I too dealt with many medical horror stories experienced by military personnel and their families. I have also read some of the legal cases filed against DuPont and the arguments presented by the plaintiffs.

However, this is not a perfect world. We need to find incentives to encourage the advancement of technology in the medical community, not discourage it. If Drs. Watkins and Mirowski did not pursue their idea of developing the AICD, I and 50,000 others like me around the world may not be alive today.

I applaud the major corporations like DuPont, Dow Chemical, and others who have done so much in the advancement of raw materials science. And, Mr. Chairman, I sincerely appreciate your taking the time to hold this hearing today and expressing your interest in this critical issue. Because of my personal interest, I, too, am working on a legal paper, trying to defend these major corporations, and your hearing will certainly help advance that.

That concludes my remarks this morning, and I will be happy to answer any questions you may have.

Senator LIEBERMAN. Thank you, Ms. Phillips. Again, I thank you for doing what is not easy and is awkward, which is to tell your story publicly. To me it is literally a phenomenal story and has all the elements of a miracle that perhaps we take for granted these days, but it goes right along with the Reilys' story. I find you, like them, to be an inspiration, really, and the most vivid indication of why it is so important to protect this industry so that others can continue to experience the miracle. I thank you, and we will have some questions afterward.

Now we have three doctors who are making these miracles occur. Dr. J. Donald Hill is the Chair of the Department of Cardiovascular Surgery at the California Pacific Medical Center. Dr. Hill, thank you for coming all the way out here. We look forward to your testimony.

TESTIMONY OF J. DONALD HILL,[1] CHAIR, DEPARTMENT OF CARDIOVASCULAR SURGERY, CALIFORNIA PACIFIC MEDICAL CENTER, ON BEHALF OF THE BIOMATERIALS AVAILABILITY COALITION

Dr. HILL. Thank you, Mr. Chairman.

I am Donald Hill. I am a heart surgeon, and I am here with Dr. Stulberg representing a coalition of medical societies to address the biomaterials availability issue. We represent our profession but, more importantly, we are speaking as an advocate of the patient.

I will not reiterate to you how we came to these crossroads in the availability of medical devices. Suffice it to say, being a supplier of raw materials for medical devices is not a good business to be in, and many are getting out. The exact extent of the problem is not yet completely defined, but on a daily basis it seems to be increasing without an alternative or practical solution.

Now the medical community can no longer treat this as somebody else's problem. Our patients are going to be affected in as little as 18 months when the supply of Dacron, as you have heard, for example, runs out. Our shortages in other areas will surface in 2 to 3 years.

My only goal here today is to provide you with information on the direct effect these shortages will have on the public who require permanent implants which contain these materials, even though they may be present in minute quantities.

So how many types of materials and what types of implants will be involved? Everybody will eventually be affected—you, me, your family, and your community. In my own specialty of heart surgery, it is estimated 700,000 patients per year needing implants will be directly affected, and another 1.7 million indirectly. This includes the following:

35,000 people per year need artificial heart valves to replace their defective valves. You have already seen demonstrated this valve has this tiny cuff of Teflon fabric on the edge which is used to suture it into the heart. Patients who need this valve, have a natural life prognosis of about 1 to 4 years if they don't receive it. With it, they have, we know now, at least 3 decades of a quality life. Not only that, the suture material that we use to sew it into the heart is made of these same kinds of material.

140,000 patients per year need pacemakers to maintain their heart rhythm. You were also demonstrated a pacemaker. It has many materials in it, one of which is a minute amount of Teflon to help protect the inner surfaces and also to protect the battery. Without Teflon, they will not be able to produce these kinds of pacemakers. These pacemakers allow people to live perfectly normal lives. They change heart rates of 40, 30 or 0 into heart rates of 70, which is perfectly adequate to have a normal life.

35,000 patients per year needing implantable defibrillators, as you have just heard presented. Here is one of these defibrillators. They are slightly larger than we would like to see, but with new ones, they will become smaller. This defibrillator has a special meaning to me. Two days ago, a professional colleague of mine visiting San Francisco from the East sat beside me for 6 hours in a

[1] The prepared statement of J. Donald Hill appears on page 138.

small, intense technology discussion with six other people. He went back to his hotel and had a cardiac arrest. Luckily, somebody was around to resuscitate him and call 911. He is fortunately OK today, and his brain is OK, but he will no doubt get one of these, probably next week.

Senator LIEBERMAN. As I understand these, when the heart—are these performing a regular function, or do they just go into effect when the heart fails?

Dr. HILL. They go into effect when the heart fibrilates. With this, you do not have to dial 911. You do not need a paramedic. It does all those things for you. It is the ambulance built into you.

Senator LIEBERMAN. That is amazing. And it is made to essentially respond at the moment of crisis.

Dr. HILL. What it does, inside of you is watch your heart every second of every day. When it does not receive the electrical information it wants from your heart, then it does what it has to do, and that is electrically bring your heart back into a normal rhythm. And not only that, it records what happened so that a physician can examine the details of the arrest afterwards.

Senator LIEBERMAN. Amazing.

Dr. HILL. 230,000 patients will need vascular grafts, which you have already seen a demonstrated, this material has now been around for 30 years. It has an impeccable history of being useful in the medical profession. There is nothing to replace it, and there are millions of people to testify to its good use. It is used for obstructed vessels in your neck, in your heart, in your abdomen, in your legs. Everywhere in your body it is used.

In brain surgery, as you have already heard, there are 75,000 people per year who receive these little silicone shunts. Without these, these children—it is mostly children—will go on to be institutionalized permanently with brain damage with no likelihood that they will ever get out of the institution. They do not die. They just continue to live in a semi vegetative state.

In urology, a variety of 2,500 incontinence devices and 50,000 penile implants are used each year.

In one's eyes, the simple act of being able to see where you are going and what you are eating, more than 1 million people per year have these tiny, little silicone implants that allow them to see and to conduct a normal life. Three thousand shunts each year are implanted in patients eyes who have glaucoma, which is an abnormal pressure in your eye. Retinal detachment, a misfortune that strikes young and old alike, 25,000 people per year.

The vast majority of these patients with medical implants will return to a productive life, and I am confident that in this room alone there are people or members of their families who have been or will be the beneficiary of some of these therapies.

These numbers are pretty sobering, and I have not reiterated all that there is. Many of my colleagues in my own specialty of cardiac surgery have dismissed this problem as impossible because of the huge effect it would have on patient care. They cannot conceive of any scenario in which this would come to pass. Nonetheless, it is happening.

What are the cumulative effects of the shortage? Certain patients will die in large numbers. Other patients will not die, but will have unnecessary pain and suffering and a poor quality of life.

The cost of health care will go up. Physicians will continue to treat their patients but will do so with less effective and more expensive technology reintroduced from the past.

We will have to spend 10 years searching and developing new biomaterials, only to have them face the same liability risks that exist today. Capital for innovation will be in short supply because medical device manufacturers will be viewed as an industry that has an unaddressed, unique societal problem—deep-pocket-motivated litigation.

Large companies who are able to pay the costs of indemnifying polymeric raw materials suppliers will gain a monopoly of the marketplace that will be more valuable than a patent position. Most device innovation originates in small companies, so the opportunity to extend the art and craft of medicine will suffer or come to a standstill, as widespread competition in the marketplace winds down.

The medical community has no motive to create an artificial crisis, as has been suggested. Our desires are twofold: First, we wish to effect a solution which will not interrupt the ready supply of currently available, high-quality implantable medical devices for our patients; and, second, we wish to promote the innovation of worthwhile new devices.

It is certainly true that need spawns innovation. But since the problem we face is societal in nature, any need-driven technical solution would face the same product liability dilemma. Substitutes are not the solution. They are a Band-aid. There must be a balance struck between protecting the consumer against poor products and not penalizing the rest of society who needs medical products to enhance both the longevity and quality of their lives. A legitimate business decision by manufacturers of raw materials used in medicine, which is often a small fraction of their overall business, is now destined to have a huge effect on the public. How far back in the chain of participation does the responsibility to the patient lie? There is something wrong with a societal process which results in the outcome we now have.

Solutions are not easy, but the medical community is unified in their support of maintaining the authority and thoroughness of the FDA in their role of controlling the safety and effectiveness of any device used in patients. We applaud any improvement in the FDA process but would resist shortcuts in the approval process.

We ask the members of this Committee and the Congress to be creative in a solution that will serve all parties, and we also ask that they act quickly because we do not have time on our side.

Thank you, Mr. Chairman.

Senator LIEBERMAN. Thank you, Dr. Hill. Again, you make a point, just to clarify for the moment, that not all, but most of these devices are approved by the FDA.

Dr. HILL. They are all approved by the FDA. Many of them for decades.

Senator LIEBERMAN. Right. Am I right? The reason I said most if not all—you correct me if I am wrong. I was under the impres-

sion that some had been grandfathered, so to speak, which came out earlier?

Dr. HILL. Yes, many are. For example, these graft materials were grandfathered after the Rogers Act in 1976. From then on, everything had to be approved. You can receive a retroactive approval if you can demonstrate that a device is substantially equivalent to one from before 1976. That is an FDA decision. They would make the decision.

Senator LIEBERMAN. And in the overall product liability reform bill that we have before the Senate, which we have now negotiated an agreement and will come up on the floor toward the end of June, the third week in June, there is a provision that would not protect manufacturers or others involved from liability for any negligence if the product had been approved by the FDA because it is still possible there might be problems with it, but at least it would protect them from so-called punitive damages beyond, to simplify, out-of-pocket costs.

Dr. HILL. Well, it would show that they had probably been responsible in the process by which they did approve it.

Senator LIEBERMAN. That is the point.

Dr. HILL. But it does not stop a person's or society's right to sue them.

Senator LIEBERMAN. Right. Thank you, Dr. Hill.

Dr. Stulberg from the Cleveland Center for Joint Reconstruction, thank you for being here.

TESTIMONY OF BERNARD N. STULBERG,[1] CLEVELAND CENTER FOR JOINT RECONSTRUCTION, ON BEHALF OF THE AMERICAN ACADEMY OF ORTHOPEDIC SURGERY

Dr. STULBERG. Mr. Chairman, my name is Bernie Stulberg. I am an orthopedic surgeon, and I am pleased to say a few words to you on behalf of the American Academy of Orthopedic Surgery.

Our specialty deals with medical care of the musculoskeletal system and has more than a 40-year history of using implantable medical devices. Our field has been characterized by intense basic and clinical research into the performance of such devices, and has been able to substantially improve the quality of life of our patients because of these devices.

I believe that we can offer a perspective to this recent concern relating to the availability of basic materials for the manufacture of devices that are used for biological implantation, and I hope that it might prove of some benefit in your deliberations.

There are three basic messages from this perspective:

The first is that any implantable device that is subjected to stress has the potential to fail over time. This is particularly true for devices used in load-bearing applications.

Secondly, the failure patterns of devices used in load-bearing capacity is usually multifactorial, involving varying contributions from device-related factors, technical factors of implantation, and biological factors, including patient usages.

Thirdly, the risk to our patients, our specialty, and to the American manufacturers of the products we use is quite substantial if

[1] The prepared statement of Bernard N. Stulberg appears on page 139.

we equate device failure with inadequacies of the base materials incorporated into these devices. Until such time as new mechanisms for device evaluation prior to and after implantation are developed and applied routinely, statutory protection will be necessary to protect suppliers of base materials. These new mechanisms will require the combined efforts of scientists, manufacturers, regulatory agencies, and clinicians to establish processes of evaluation that limit the exposure of patients to what ultimately become poorly performing implants.

While the base materials that have been pulled off the market by DuPont and Dow Corning have only a small impact on the orthopedic marketplace, we do have a number of materials that we presently use in orthopedics for a variety of applications that might be placed in similar jeopardy if the suppliers of these materials choose to withdraw from the medical marketplace. Perhaps our most exposed material is that of ultrahigh molecular weight polyethylene, an important component of prostheses used for artificial joint replacement.

Approximately 450,000 patients per year undergo replacement of the hip or the knee joint in the United States. Each of these has a portion which is fabricated from a high-strength metal, which ultimately mates to a surface of ultrahigh molecular weight polyethylene. I think it could be of help in understanding our concerns if we could use the example of hip replacement devices.

Total hip replacement surgery is used to treat end-stage arthritis of the hip joint, used to treat fractures to the upper part of the femur, problems related to blood flow abnormalities of the hip, tumors involving the hip joint, and a host of other applications. It provides predictable pain relief and substantial improvement in the function of the joint and allows restoration of the patient's quality of life. Approximately 60 percent of these procedures are performed in patients over the age of 65. The operation itself is performed about 250,000 times a year.

The area of greatest concern at the present time with hip replacements is the wearing of the polyethylene portion of the replacement. Prior to 1968, devices used for hip replacement looked much like this device: a large ball mated to the patient's own socket cartilage. This proved less satisfactory in that it wore the cartilage and could actually wear through the bone. In addition, it was not predictably anchored to the bone itself.

The hip replacement represented by this device was initially made of stainless steel, and it was mated with an all-plastic component, which was of ultrahigh molecular weight polyethylene. These components were anchored to bone using bone cement. With time, we found that some of the devices were not strong enough, and new materials and processes to manufacture the metal alloys were devised. Now most components are made of either titanium or chrome cobalt alloy implant.

We also discovered that cement could become brittle, fragment, and cause debris, leading to excessive bone loss and accelerated wearing of this plastic. In addition, the plastic could wear just from the movement of the parts. Thus, we moved to newer devices that would address these problems. These required substantially greater sophistication in manufacturing, metallurgical processes to manu-

facture these devices, and newer ways to use the polyethylene. These approaches have resulted in markedly improved devices, improved predictability of the operation, and so much so that the indication for the use of these devices has expanded. Indeed, many of these devices can be placed in patients where the stresses on the devices are greater than ever have felt to be reasonable for these devices, and probably none more notable than that placed in a famous baseball player.

Polyethylene is still an extremely important component of these devices. We have had to try new approaches to try to anchor it directly to the bone. It turns out these approaches have had a negative impact on the performance of this device from a clinical standpoint, even though the initial laboratory testing suggested they might perform equally well, if not better. In one series, we have seen evidence of wearing of this particular device in as many as 50 percent of the patients by 7 years, a rate of wear that is nearly twice as fast as what we were experiencing previously.

Now, at present, the supply of this polyethylene is from two sources. The percentage of the polyethylene that the manufacturers produce that goes to the medical marketplace represents about one-half of 1 percent of its total output. If for liability reasons the manufacturers were to withdraw from the medical marketplace, we would be forced to return to approaches used before 1968. This would have the impact of undermining the $10 billion industry associated with joint replacement activities, would likely drive most of the industry offshore, and might make us entirely dependent on manufacturers outside the United States.

The point we wish to make is that none of the materials we use is perfect. As we identify problems in certain applications of these materials and address them directly, we run the risk of compromising performance of other aspects of the devices. There is likely to be either a biological or biomechanical consequence, or perhaps both, to each material we use in a biological environment. It is clear that there are factors relating to device failure that physicians may not be able to completely control—the biological factors such as infection, rejection, or corrosion. But there are also factors that clearly can be controlled by the physician, such as the implantation of appropriate components in the appropriate patients and in the proper position. There are also steps that must be taken by the manufacturer, such as qualification of the materials selected to be placed in devices, proper shaping of the devices and proper characterization of the devices and their materials after devices have been fashioned.

Each of these areas has an impact on how that material will perform once it is implanted.

We believe it is important to identify those areas of the medical industry that have this precarious relationship of high risk with low return, and to provide them with statutory protection. It will be similarly important to work toward newer methods to predict and ensure safety of devices over extended periods of implantation and to provide a cooperative regulatory environment that stimulates their development.

Thank you very much, Mr. Chairman.

Senator LIEBERMAN. Thank you very much, Dr. Stulberg. I look forward to coming back to questioning you.

Finally, Dr. Galletti, who is Professor of Medical Science at Brown University. Thank you for being here.

TESTIMONY OF PIERRE M. GALLETTI,[1] UNIVERSITY PROFESSOR AND PROFESSOR OF MEDICAL SCIENCE, BROWN UNIVERSITY, AND PRESIDENT, AMERICAN INSTITUTE FOR MEDICAL AND BIOLOGICAL ENGINEERING

Dr. GALLETTI. Thank you, Mr. Chairman. My name is Pierre Galletti from Brown University in Providence, Rhode Island, where I am the head of the Artificial Organs, Biomaterials and Cellular Technology group. Since 1957, I have been involved in artificial organ and implant research first at the Cedars of Lebanon Hospital in Los Angeles, then at Emory University in Atlanta, and lastly at Brown University.

I speak here as president of the American Institute for Medical and Biological Engineering, an umbrella organization which includes 320 elected fellows who are the senior scientists in the field from academia, industry, and Government; 46 university-based programs in biomedical engineering; and 12 specialized bioengineering societies with about 20,000 members. The institute was established for the purpose of unifying the bioengineering community and promoting the engineering approach for enhancing health and quality of life through innovation and appropriate use of technology. The institute focus is on development of public policy. We have concluded that the recent embargo on biomaterials used for the fabrication of implantable devices is a major public policy issue which threatens the care of critically ill patients, endangers innovation and scientific progress in basic and clinically oriented research, and affects competitiveness and employment in an industry segment in which the United States currently has the undisputed leadership.

Our position and our perspective on the biomaterials crisis is expressed in a letter to the editor of Science Magazine published in today's issue of that journal, and allow me to quote a few words from that: ". . . materials which are reasonably biocompatible with use in the human body . . . are . . . increasingly difficult to obtain from primary producers and may soon disappear completely from the U.S. scene. The reason is that chemical companies such as DuPont, Dow, Dow Corning and others have determined that unpredictable and excessive liability costs of doing business with manufacturers of medical devices no longer justify unrestricted sale of standard polymers to these customers. Under current U.S. product liability laws, any remote supplier of commodity materials can be joined in lawsuits involving medical products which are alleged to have failed unexpectedly, not lived up to expectations, or caused complications."

Since the sales of such materials represent but a tiny fraction of the business of chemical companies, but account for a major part of their legal costs, it is more expedient for them to opt out of the medical device market.

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[1] The prepared statement of Pierre M. Galletti appears on page 141.

This embargo, which already affects the main source of fluorinated polymers such as Teflon, polyacetals such as Delrin, silicone compounds, polyurethanes and polyesters such as Dacron, is progressively extending to other elements of medical devices. For instance, the small but essential amount of Teflon powder which enters into the fabrication of batteries for cardiac pacemakers, the electric components of such devices, as well as the specialty metals used for pacemaker casings and joint replacement prostheses. The resulting crisis could bring to a halt the fabrication of implantable devices in the U.S., resulting in a shortage of widely used, FDA-approved devices on the U.S. market, inadequate treatment for thousands of patients, and the loss of jobs in a major sector of U.S. industry. Other potential consequences include a shortage of materials for artificial organ and cell transplantation research, the loss of engineering and medical expertise as material fabrication and clinical trials are shifted abroad—that is currently the case—the closing of career opportunities for graduates of U.S. training programs, and a diminished incentive to develop new materials since the know-how of industry is needed to assure quality-controlled production.

This is a complex situation which increasingly resembles the crisis already faced by the U.S. small aircraft manufacturers, most of whom have gone out of business or bankrupt because of liability losses. The same crisis and the same fate threaten the U.S. medical device industry.

In the short run, the most effective remedy would be to change tort law to bar product liability claims against remote suppliers of off-the-shelf commodity materials and components of devices which have received FDA approval. The entire liability burden would then fall on the device manufacturers, who could decide whether or not to produce a device.

Better solutions may be generated through discussion with all involved parties. However, a temporary resolution is urgently needed if we are to avoid a shortage of chronic implants for critically ill patients.

I would like now to dispel some common misconceptions that relate to the field of biomaterials for chronic implants and conclude by suggesting some steps that could be taken to alleviate the impending crisis.

First, some facts to keep in mind when addressing this issue: The overwhelming majority of materials incorporated into chronic implants are standard, commodity plastic, metals or ceramics widely used in non-medical products. The term biomaterial is only justified inasmuch as these materials meet definite, stable specifications and are processed and potentially modified to fabricate implantable or blood-contacting devices. Therefore, clinical biocompatibility characterizes the entire assembled device and cannot be assumed from its constituent materials.

Second, there is no such thing as a universally biocompatible material for all applications. The very same polymers which function satisfactorily in one type of implant—such as the Teflon mesh in the suture ring of a cardiac valve that we have heard about—can prove disastrous in other applications, for example, the same Teflon in the articular surface of a temporomandibular joint.

Third, the quality and reproducibility of polymeric materials used for chronic implants—such as Dacron® polyester for vascular grafts—is directly related to the amount produced and the experience of the manufacturer. Since the quantities used for medical devices are vanishingly small compared to other industrial applications, it is not surprising that reliable materials have largely been obtained from major suppliers of chemical products developed for non-medical uses. It is not impossible to fabricate reliable polymers on a small scale, but the cost will be orders of magnitude higher than is presently the case.

Finally, we should not forget that the body environment is warm, humid, and corrosive, and that under such harsh conditions, some degradation is unavoidable in chronic implants. Unrealistic expectations all too often cloud our evaluation of replacement parts for the human body. Wear and aging affect the implant as much as they affect the person who receives it. The concept of a permanent failure-proof device is an ideal to strive for, but it is currently unobtainable. In this regard, it is paradoxical that we should hold chronic implants to a higher standard than drugs, where side effects and failure to achieve the desired effect are, within limits, broadly accepted.

What recommendation can I formulate to meet the biomaterials crisis? Ideally, measures should be taken to convince remote suppliers of commodity materials or components for medical devices to keep them available to the U.S. medical device industry. This may require a narrowly defined change in the law to provide relief or remedy for ultimate liability claims against providers of standard, off-the-shelf elements of approved devices.

Second, the National Institute of Standards and Technology could undertake collaborative programs with industry to target R&D and create a strategic reserve of materials which are essential for the manufacturing of medical devices and have proven life-saving for critically ill patients. This would establish reliable sources of standardized, specifications-meeting, quality-controlled commodity polymers designed to interact with blood or other body tissues.

Third, the Food and Drug Administration, in concert with other Federal agencies, should build on the data bases which will result from the federally mandated medical device tracking system to develop a national implant data retrieval and analysis structure. Such information will allow statistically valid evaluation of chronic implants, and the materials and components thereof, and provide a perspective on patient-related versus device-related failures, which are often confused.

Lastly, the National Institutes of Health should prioritize programs that expand the science underlying the clinical use of chronic implants. This would include the mechanisms of degradation of biomaterials, the fundamental processes of the interactions between materials and body tissues, the individual and species-specific difference in bioreactivity to materials, and the development of non-invasive implant monitoring techniques applicable to man.

Hopefully out of the present crisis will come better insights into the success and failure of implants, better rehabilitation of critically ill patients, and preservation of therapeutic approaches for which there are currently no substitutes.

Thank you for the opportunity to express these thoughts to you today.

Senator LIEBERMAN. Thank you, Dr. Galletti, and thank you for those specific and I think very constructive, thoughtful suggestions at the end. I would tell you that the legislation that we have released in draft form this morning follows quite directly the suggestion that you make for a legislative remedy, but I think your other suggestions are quite good as well. And I would invite members of the panel and anyone else here or within hearing to take a look at the proposed legislation, and I would welcome your advice on it.

There are a lot of different ways we can go at this. I will introduce it as separate legislation. I might introduce it as an amendment to the product liability bill when it comes up. And, in fact, I might well introduce it as an amendment to the health care reform legislation when that comes up, because this is so fundamental to the quality of health care.

Anyway, I wanted you to know, Doctor, that I appreciate your suggestions.

I have just a few questions for this panel because your testimony has been excellent. Perhaps I would ask Mark and Peggy, one of the things that has struck me as I have gotten more deeply into this problem now, or crisis, is the number of people who are benefiting from implanted medical devices, and the testimony of Dr. Hill documented that. I saw one total number that suggested there are almost 7.5 million people in this country with one form or another of medical device that is sustaining their quality of life, if not their life itself.

I wonder, have those who are users of the devices begun to organize as advocacy groups, particularly in response to this crisis, or just generally to share experiences and be mutually reinforcing?

Maybe, Mark, you would start.

Mr. REILY. I would say, yes, they are beginning to organize and have probably been aware of the problem for perhaps about a year. And there are already groups that are formed for hydrocephalic patients in Thomas' case. So, yes, they are getting together, and they are starting to form. Obviously their focus is on trying to alleviate the problems we are talking about today.

But I would say it is at an early stage.

Senator LIEBERMAN. Ms. Phillips, do you want to add anything?

Ms. PHILLIPS. I am not aware of any for the AICD or heart devices. I do know that at Washington Hospital Center, where I had my device implanted, they have a support group. Unfortunately, the meetings are during the day, and I am not able to go since I work full-time.

Senator LIEBERMAN. Right.

Ms. PHILLIPS. But they perhaps would be a good network to start looking into something like that.

Senator LIEBERMAN. And if I remember correctly, you said that to your knowledge there are approximately 50,000 people in the country who have the AICD's, the automatic defibrillators?

Ms. PHILLIPS. Yes, sir. That is around the world.

Senator LIEBERMAN. Around the world.

Ms. PHILLIPS. Yes, sir.

Senator LIEBERMAN. OK.

Dr. Hill and any of the other doctors, let me ask this question. We have been talking, I think appropriately so, about medical implants in a very positive way because of the obvious effect, positive effect they have had on the lives of people who are here and millions of others who are not here. But we also know from some high visibility cases that sometimes implants do not work, and the most notable case that may be in the mind of the public now is obviously the breast implant cases.

I wonder if any of you would want to talk about those to distinguish those from the cases we are talking about. I know, for instance, that the breast implants did not receive FDA approval, so that is one significant differential from the cases we are talking about now. But are there any other points of distinction for people who may be listening to the hearing?

Dr. Hill, do you want to start?

Dr. HILL. Well, one of the examples I could give, perhaps, is in reference to the valve, and from the standpoint of the manufacturer and the physician, this is a uniquely designed valve. And if the design was wrong or the manufacturing was wrong, that would be a unique responsibility of the manufacturer and not related to the primary biomaterial.

We would not want to see—the medical profession would not want to see anything happen that would change the responsibility of the manufacturer to what he does and how well he does it. That is absolutely crucial, and when a bad product arises, whether or not it was from human error, intentionally or unintentionally, it has to be corrected, and there has to be recourse from society for their damages.

However, when there is no human error involved and when it goes back up the chain, I do not believe and I do not think most of the people in the medical profession believe that those people can be held accountable. The only thing that they should be accountable for is that the material that they sell you is what they say it is and that they tell you everything they know about it. And then it is the responsibility of the manufacturer of the material to be sure to qualify it to be what it is and then to use it and qualify it in medicine. And if that manufacturer does not properly qualify it, he should be held accountable. But the responsibility, I believe, has to start there.

Senator LIEBERMAN. I think you stated it very well. None of us is trying to protect a manufacturer or, indeed, a supplier from liability or responsibility for doing something negligently. It is the excess here and the going up to the chain to people who have met the specification. I think that is an important point.

Dr. HILL. There is one other point that might be made, because of the success of technology in the last 40 years, the public has an expectation that we can always do everything and nothing should go wrong.

Senator LIEBERMAN. Right.

Dr. HILL. Even without human error or misjudgment, things will sometimes go wrong. When they do, it is because technology has a limitation of what we can do, and when we bypass that limitation, sometimes patients are injured.

Senator LIEBERMAN. Yes, absolutely, and that really was my second question to invite you to talk about. I think our discussion earlier—these are miraculous. I think when sometimes we are in the middle of an experience, obviously you do not appreciate it. When the history of this time is written and there have been so many remarkable achievements in our time, I think as you look across the span of history, some of this work that is being done will be seen as the most remarkable of the achievements in the sustaining of life by essentially artificial devices that are implanted as a result of our knowledge.

On the other hand, because these are such phenomenal achievements and miraculous achievements, there remain elements of risk associated with those. And I appreciate what you said just now. I do not know if there is anything more to say about it, Dr. Galletti or Dr. Stulberg, but clearly when patients—you know, Ms. Phillips did not have much of a choice, really. And thank God everything worked out well. But how do we describe the risks to patients as they come to this point?

Dr. GALLETTI. Maybe we have to teach patients that none of those devices will render them immortal. There is a sort of an idea that if you can replace every part of the body which fails, one after the other, we will become like an old DC3 which is made entirely of spare parts and keep flying 25 or 50 years after it was first built. That is not true. We are aging. There is an inexorable process of wear and tear in the human body, and putting devices in the human body will not interrupt that process. It will repair or control acute accidents which occur in the course of life, but eventually there is not much we can do about the final decay of our body structures. And I think we have to remain realistic.

But with all of the emphasis on the miraculous aspect of some of those devices, which is absolutely correct, at the same time we have to be careful not to raise undue expectations.

Senator LIEBERMAN. Dr. Stulberg, do you want to get into this? In some sense, we think of the work that Dr. Hill may do with the heart valve implant as much more directly related to immediate life and death as opposed to joint reconstruction.

Dr. STULBERG. Right.

Senator LIEBERMAN. So the decision for you and your patients may be somewhat more complicated.

Dr. STULBERG. I just would like to underscore two points that have been made. One is that there is a difference and the medical population perceives a difference between a supplier of a material and a manufacturer of a device. While the device itself represents use of a particular material that has been tested, it must be tested as a device as well.

The second point from an orthopaedic perspective, most of our devices are implanted for long periods of time, and these devices see stresses in weight-bearing joints that can be easily 3 to 5 times body weight, cycling a million times a year. So these devices see enormous stresses, and it is not that scientifically they have not been looked at. It is just that biological environment may change the way they behave, and you cannot always predict that. So it is going to be necessary as well to look at ways of documenting 10,

15, 20 years down the road how devices are performing, and we are not good at that yet.

Senator LIEBERMAN. I do not have any further questions. Mr. Reily or Ms. Phillips, do you want to add anything based on what you have heard?

Ms. PHILLIPS. Mr. Chairman, I have a list that was given to me of some materials used in implantable medical devices that are going to be subject to withdrawal that I would be happy to provide for the record.

Senator LIEBERMAN. I appreciate that, and we will print it in the record.[1]

Ms. PHILLIPS. The suppliers include Dow and DuPont and some of the materials are Dacron and Teflon. The list also shows what they are used for.

Senator LIEBERMAN. Let me thank all of you. This panel has been very helpful, and I appreciate very much that you came forward. Mr. Reily, I do not know how much time you have in Washington or whether you have been here before. I do not know what the exact nature of the bribe was, but I would tell you that the National Zoo is a great place to visit when you are here.

Mr. REILY. Thank you very much.

Senator LIEBERMAN. Kids love it.

Thanks very much. Good luck. God bless you.

Senator LIEBERMAN. The final panel, final witness, will be Kristen Rand, counsel for Consumers Union. Ms. Rand, thanks for your patience in coming on as the last witness. We appreciate your being here, and we look forward to your testimony now. We know you have a somewhat different view of the general subject of product liability reform, but we wanted to give you an opportunity to be heard this morning.

TESTIMONY OF M. KRISTEN RAND,[2] COUNSEL, CONSUMERS UNION

Ms. RAND. We appreciate that very much, Mr. Chairman. I am Kristen Rand. I am counsel in the Washington office of Consumers Union. We are the publisher of Consumer Reports Magazine.

I am testifying today also on behalf of Public Citizen's Congress Watch and the Consumer Federation of America. All of our organizations appreciate the opportunity to share with you our views regarding the problems of medical device materials suppliers.

Consumer access to safe, effective medical devices is of great concern to all of our organizations. We recognize that many people's health and even lives depend on the continued availability of well-designed and safe medical devices. We are also aware of the problem of manufacturers refusing to supply raw materials that are critical in the production of a variety of devices. And at least one of my colleagues from the consumer community has met with a device manufacturer to explore this issue.

We are committed that if there is a danger that consumers will be denied access to safe medical devices because of the lack of availability of raw materials that is indeed a problem, and we

[1] See page 154.

[2] The prepared statement of M. Kristen Rand appears on page 143.

would like to work with you to find a solution to this problem. But before we rush to implement changes that might seriously affect device regulation or the civil liability system, we need answers to the following questions: Does a problem really exist? And this hearing has gone a long way towards convincing me that this is a real problem. And if it is, what exactly is the scope of the problem? And what remedy is warranted?

We just want to make sure that any remedy implemented is not overly broad and does not needlessly dilute the civil liability system. And the reason for our caution is explained by our experience in the area of medical device regulation.

The past few decades are replete with examples of manufacturers making assurances to Congress and the public that a particular device is safe and claiming that its availability is threatened by the product liability system. When we have investigated these specific examples, we have almost without fail discovered that the device at issue is unreasonably dangerous or defective.

This experience has forced us to be skeptical and not accept at face value the claims made by the device industry and manufacturers.

For example, the Vitek, which has been referred to earlier, was offered in a past Congress—as a victim of the product liability system, it was alleged that it was safe and was being driven off the market by excessive product liability. We now know that that device was defective.

I also would just like to say a word about the costs associated with this litigation in that it is our view that the product liability system is not the prime source of litigation costs, but empirical data shows that suits by firms against one another in contract disputes far exceed those of product liability suits. And I would like to offer this article from the *Wall Street Journal* to be made part of the record.[1] The opening sentence states the problem succinctly: "Businesses may be their own worst enemies when it comes to the so-called litigation explosion."

Senator LIEBERMAN. Were those contract disputes related to negligence or——

Ms. RAND. No. They are just your standard contract disputes where businesses enter into contracts, and this actually has a graph that shows that product liability suits are dwarfed by just general contract disputes. I think you might be interested in looking at this in more detail.

Senator LIEBERMAN. I think you would agree that in the case we have talked about, in the DuPont case, clearly the concern of DuPont and the other raw material suppliers here is not related to contract disputes, but related to their fear about product liability suits.

Ms. RAND. I understand that, but my point is that we think there is too much focus on the product liability system when there are other aspects of the litigation system that deserve scrutiny. And I would also point out that in DuPont's case, I understand that they are being dismissed from these suits where they were the supplier for the raw materials for Vitek and that they must repeatedly show

[1] See page 155.

that they did not know of the danger or that their component was not defective, and that consumers have that same problem in suits where they pursue suits involving the same product and have to repeatedly prove the same facts.

So there may be something there that we could explore that would address both of those problems.

Senator LIEBERMAN. Obviously I do not disagree that there isn't too much litigation in this society generally. There is. But that fact, at least in my response, does not diminish the particular effects that we have heard described today of product liability litigation.

Ms. RAND. Well, I understand the specific point, and I think that working together we can probably come up with a narrowly tailored solution that gets at the problem where there is a component that we know is safe and that there are repeated suits on exactly the same fact pattern. I think that is what we are talking about. And the consumer community is not interested in court resources being expended in relitigating the same issue over and over again, but we do want to maintain the ability of consumers to pursue lawsuits if there is a reasonable belief that a component or product is unsafe or defective.

Senator LIEBERMAN. Yes, understood. And, again, not to belabor it, I want to give you an opportunity to give your testimony. But there are different ways in which people are consumers. I understand and respect your right to protect—your interest in protecting the right of consumers who suffer from negligence and negligently made products to sue and be reimbursed. But obviously Ms. Phillips, Thomas Reily, and millions of others who have the implanted medical devices that are so important to them are also consumers. And we want to protect them from the loss of access to those products as a result of fear of suppliers of too much liability litigation.

Ms. RAND. Well, we completely agree with you that consumers' access to safe medical devices must be maintained, and that is one reason we are thankful to be part of this process, because if this really is as severe a problem as it on its face appears, we would like to work to find the solution. Because, obviously, access to devices that are life-saving is as important as access to the courts if you are the victim of a defective device.

Senator LIEBERMAN. Absolutely. Why don't you go ahead? I will try to control my interventions.

Ms. RAND. My testimony walks through some of what has been proposed in the context of the broader product liability legislation, and I will not belabor those points. I will just conclude by saying that the consumer community views civil liability for manufacturing and marketing dangerously defective devices as an irreplaceable incentive for the production of safe medical devices.

We also think that Federal regulation of medical devices by the FDA is inadequate. There are many cases of defective devices that have slipped through the approval process. Therefore, we feel very strongly that any action designed to remedy problems that device manufacturers may be experiencing with suppliers must not consist of blanket liability shields. We have not yet had a chance to look at your draft legislation, and we will be happy to do that and give you our comments on it. We hope we can engage in a constructive dialogue to find an answer to this problem.

Thank you.

Senator LIEBERMAN. I thank you, Ms. Rand, and I appreciate the spirit of your testimony. I would look forward to working with you and the other consumer groups to see if we can come up with a solution that protects the broadest understanding of the rights of consumers as we have described them.

You know, the continued active role of FDA in all this is very important, and as you know, the broader product liability reform legislation, S. 687, which is before Congress, does put a fair amount of emphasis on that FDA approval.

They are not easy. They are there to protect us, and we want to make sure that those who do not follow the FDA procedures are in that sense not protected. And, again, I would point out the breast implant case where the FDA did not grant its approval, and there are other cases where FDA approval may have been received, but then other FDA directives were not followed, such as the case of the injectable bovine collagen which you refer to in your testimony.

But let's agree that we will look forward to your comments on the proposed legislation. I appreciate the fact that you have been here all morning listening to the testimony and feel that—I am not trying to put words in your mouth—at least it appears a case has been made that you do not want to deny consumers access to these devices. And I hope we can come to a recommendation and a remedy that we all can agree on. So I thank you for that.

Ms. RAND. Thank you, Mr. Chairman.

Senator LIEBERMAN. I thank all the witnesses. We are going to leave the record of the hearing open for 2 weeks. We may have some additional questions for the witnesses. You may have some additional statements that you would like to put in the record. But, again, in my opinion, the case is really a clear one that we have these miraculous devices that are keeping people alive and improving the quality of life, that these devices are now, by my hearing of this testimony, definitely endangered by the decisions made by raw materials suppliers as a result of their fear of lawsuits. And we simply cannot let this happen. There is too much on the line. And I am committed to seeing if as part of product liability reform or health care reform this year that we make sure that we avoid this crisis and keep people healthy and, incidentally, keep people employed in this important industry.

I thank everybody for a very constructive morning. The hearing is adjourned.

[Whereupon, at 12:00 p.m., the Subcommittee was adjourned.]

APPENDIX

PREPARED STATEMENT OF PAUL CITRON

Good morning, Mr. Chairman and Members of the Subcommittee. I am Paul Citron, VP Science & Technology for Medtronic, Inc. Among my responsibilities is assuring that our company is technologically positioned to develop and produce high quality innovative products that treat disorders of the circulatory and neurological systems. Medtronic, by the way, is a leader in producing therapeutic medical devices to improve the cardiovascular and neurological health of patients around the world.

It has only been 40 years since the first development of medical device technology which has allowed physicians to effectively replace body parts that have been damaged by disease. A progression of innovative therapeutic technologies have restored health to millions of patients in the U.S. and around the world.

The brief history of medical device breakthroughs begins in the 1950s when large diameter vascular grafts permitting the replacement of dangerously weakened major blood vessels were first developed. In 1958 the first electronic device, the cardiac pacemaker, was implanted. This revolutionary technology stimulated hearts with too slow a rate—to a rate approximating normal. With this technology, the heart was once again able to pump sufficient quantities of blood to meet the majority of the patients' hemodynamic requirements. Without pacemakers, patients typically experience sharply limited ability to conduct daily living tasks, suffer from fainting episodes, and experience premature death. The 1960s saw the emergence of the mechanical heart valve as a practicable replacement for defective natural valves. Implanted medical devices such as these offered therapy where previously none was available. In many instances, they offered patients the possibility of saving and enhancing their lives. Perhaps the clearest example of the life saving capacity of medical devices has been the development of implanted defibrillators. This emerging technology is capable of detecting dangerous heart rhythms which can lead to fibrillation—or detecting the fibrillation itself—and automatically delivering a precise shock to the heart to restore normal rhythm. Carefully selected patients who receive such devices would have been likely victims of what is aptly known as "sudden cardiac death syndrome." Instead, they have been able to lead longer productive lives. But the increasing unavailability of materials used to produce these critical technologies jeopardizes their future availability.

It is important to note the hostile biological environment in which implanted medical devices must function. The body has created a formidable set of defenses against foreign materials. The body recognizes these materials as being potentially dangerous and vigorously sets out to consume, destroy, or isolate them. These defenses work well. Unfortunately, the body does not recognize medical devices as allies and seeks to destroy them as if they were deleterious rather than beneficial. Only a limited number of specialized materials such as certain polyurethanes, a small number of other polymers, solid silicone rubber, and an equally small number of inert metals and exotic alloys have been found, when used in properly designed devices, to be clinically acceptable for direct implantation and contact with tissue and body fluids. These materials are used to construct the implant itself or serve as the protective barrier to shield other components which are not themselves clinically acceptable for implantation. Without such materials therapeutic implants would not be possible.

As if the requirement of clinically acceptable tissue responses was not enough, implantable materials must also be biodurable. That is, they must have intrinsic physical and mechanical properties to withstand the rigors of the application in which they are used. As an illustration of this, a prosthetic mechanical heart valve is expected to function flawlessly for the patient's lifetime while being subjected to wear forces and large pressure-induced forces as it opens and closes. It is not unrealistic for a valve to experience in excess of 600 million opening and closing cycles.

It must do this without mechanical failure and without substantially damaging blood cells or causing other serious complications. These are challenging requirements which are being met with today's technologies. Even though performance is excellent, there is room for improvement. The perfect implant has yet to be developed. The device industry must have access to new and better materials and components to continually advance performance and, in this way, improve health care.

The impact of medical devices has been profound and far reaching. A 1994 study shows over 5.5 million U.S. patents annually are affected by life-saving or life-enhancing medical device technology. In the cardiovascular arena alone, over 1.2 million procedures are performed each year to open blocked arteries with balloon angioplasty, restore heart rhythms with implanted pacemakers and defibrillators, provide respiratory and circulatory support during open heart surgery, and repair blood vessels with synthetic grafts. This industry has global significance and is one of the few in which the U.S. has a positive trade balance. Current estimates are that the U.S. medical device industry will produce a $4.1 billion favorable trade balance on $40 billion in annual sales. The best measure of the effect of medical device technology, though, is in terms of how it improves and sustains patients' lives. We must never forget this.

In spite of the enormous contribution medical devices have made to the public health, the manufacturing of these products is a business that frightens many. This fear is largely a consequence of the possibility of liability exposure in the event a device malfunctions or fails. As with other business enterprises, the specter of product liability in medicine is peculiar to the United States. Its influence is growing and is having a chilling effect on innovation. Ironically, the shadow of product liability may actually be serving to keep better performing products from the market rather than being a force for improvement for the following reasons.

First, medical device manufacturers must rely on components and raw materials manufactured by other firms in order to produce their end-products. The majority of devices integrate a broad range of technologies. In many instances, these are components which are being produced for other commercial applications but have also been qualified by device manufacturers for use in medical applications. For example, in order to secure mechanical valves to the heart, a fabric sewing ring must be used. The valve is quite literally sewn into place by the surgeon by suturing through the fabric sewing ring into heart tissue. Certain polyester and polytetrafluoroethlene (PFTE) fibers have been shown to be suitable for this use. To the best of our knowledge, there have been no adverse clinical events associated with the fabric or fiber. And yet, a key manufacturer of the fibers has notified the heart valve industry that it will actively discourage the use of its material in permanently implantable products. The company concluded that selling raw material could not be justified in light of the risk of litigation associated with having their raw material in these valves.

As other witnesses will testify to, raw material suppliers are named in product liability cases even when they had no direct involvement in the design, specification or manufacturing of the product, simply because they are another possible source of compensation. Despite the fact that they are usually able to prevail on the merits, the cost of proving themselves not to be liable and the negative publicity they receive far outweighs any revenues they receive for the materials they supply. The worldwide polyester yarn market is estimated to be over $9 billion in annual sales, while the implant market for these fibers for the entire medical device industry is less than $200,000. Analogous ratios exist for other polymeric materials and components. Sales to the device industry are relatively inconsequential. On the other hand, the cost of defending against lawsuits runs into the millions of dollars.

Because of the increasing unavailability of materials and components for life-saving medical devices, the industry is now engaged in an all-out effort to find and qualify equivalent replacement materials and sources of supply. To the extent we are successful, the resources expended on these initiatives will merely get us back to where we were. We will not have advanced the state of the art. Some would suggest that the departure of the leading specialty chemical companies from selling materials to implant manufacturers may even lower the overall quality standard of the portfolio of implantable materials as smaller, undercapitalized and less sophisticated supply sources step in and attempt to fill the void. The flow of new materials which would permit as yet unmet clinical needs to be addressed will be markedly slowed. The exiting companies have the laboratories from which future breakthroughs would have likely occurred. This is not to say all progress will cease, but rather, it will be significantly slowed.

We face a real and imminent danger that high quality life saving and life enhancing medical devices will become unavailable because critical materials and components are made unavailable. For patients, the consequences can be tragic. A remedy must be found which will provide the protection necessary to assure that suppliers

will continue to provide materials to manufacturers. Unless such a remedy is put in place, we will experience inexorable declines in medical device innovation, quality, global competitiveness, and—most distressingly—the public health as certain patients are not able to obtain life-saving and life-sustaining technology.

PREPARED STATEMENT OF ELEANOR GACKSTATTER

Mr. Chairman, my name is Eleanor Gackstatter, and I am president and chief operating officer of Meadox Medicals, Inc., a medium-sized U.S. company that employs 600 people. Located in Oakland, New Jersey, Meadox has been privately owned and operated by William J. von Liebig since 1961.

I appreciate the opportunity to testify here today, Mr. Chairman, on an issue that threatens the future of dozens of medical device companies and the well-being of millions of patients the world over. I refer to the impending shortage of raw materials used in manufacturing many implantable medical devices. This is a major health care crisis, and time is quickly becoming the enemy for American surgeons in vascular, cardiothoracic, and general surgery—and, most importantly, the patients they serve.

Meadox Medicals was involved in the early days in development work using DuPont polyester yarns for implants, as bypasses for arteries. Since that time, the company has dedicated its efforts to being a specialty manufacturer of products for vascular and thoracic surgery. Through the years, polyester yarns have served this area of medicine well. Today, nearly 100 percent of Meadox's line of vascular grafts and fabrics are made of polyester yarns. Research & Development for improved treatment and use of those yarns has been a major focus in the company and is closely aligned with the requests and demands of the company's customer base—vascular, cardiothoracic, and general surgeons.

In late 1992, however, medical product manufacturers such as Meadox were given notice by their polyester yarn suppliers—in our case, Dupont—that by January 1993 all supplies of this material would be stopped. Why? Because raw materials suppliers no longer wish to confront the threat of litigation that can consume millions of dollars because of products that represent a very small part of their total business. *This is the crux of the present crisis.*

Meetings between Meadox and DuPont yielded agreement that a three-year supply of Dacron® polyester would be provided, based on Meadox's traditional usage of the material. We must have polyester or an acceptable substitute material, in order to continue manufacturing vascular grafts and fabrics. Since the time of DuPont's notification, Meadox Medicals' efforts to find alternative supply sources have been exhaustive and expensive. Those efforts have also had a huge impact on company R & D resources.

In 1994, Meadox Medicals, Inc. has budgeted its R & D at double the industry average, as a percent of sales. A significant amount of those R & D monies are dedicated to polyester yarn replacement. We are spending valuable time looking for alternatives to a material that has served the American public well for more than 35 years. Resources are being taken away from the search for new and better utilization of yarns that would yield improved or innovative products.

As a company, survival comes before the future, but how can we measure the loss created in the future for American surgeons and their patients, by our actions today? when supplies are vanishing, how can we choose to provide R & D supplies for future innovative products when the surgeon needs our products to save a life today?

If you consider the uses of the products Meadox makes, you can easily understand the importance of the company's commitment to this specialty:

- artificial blood vessels for replacing diseased arteries;
- fabrics for patching holes in the heart;
- cuffs for heart valves so that they can be sutured to the body, primarily with polyester sutures;
- conduits or tubes so that valves can be placed inside;
- fabrics for repairing hernias; and
- most critically, the vascular graft used to replace a ruptured artery in abdominal aortic aneurysms (AAA).

Aneurysms are the 13th leading cause of death in the United States, and the incidence is rising as the population ages. AAAs kill approximately 10,000 people a year in the United States. Twenty-four percent die before reaching the operating room. Only 50 percent of those who do reach the operating room live. At this moment of medical crisis, there is no time for the surgeon to search the patient's own body for

a replacement artery. There must be an artificial graft on the shelf at that precise instant, ready to go. If we cannot find a way to resolve our raw materials supply problem, that shelf may well be empty in the future. We have reason to believe that demand for this product will grow. Screening for earlier detection of aneurysms, for example, has shown that more aneurysms of all sizes were diagnosed from 1971 through 1980 than in the previous two decades.

As a leader, in our segment of the medical device industry, Meadox Medicals is stepping forward today to inform the public of this supply problem because its major shareholder determined it was critical—and ethical—to do so. Companies who use even smaller amounts of these materials for component parts of medical devices may not have yet felt the crunch. But they soon will. This is an equally troublesome situation.

Meadox intends to keep working closely with its surgeon-customers as it has through the years. Internal processing for the most efficient use of its supply of polyester yarn is a major focus. But if there is no immediate or interim solution to this availability issue, we must all be concerned with the gap being created—the gap between the time required to find alternative sources and the time required to do the testing to show equivalency to the present polyester yarn.

Once testing of alternate materials is done, the time required to win government approval of those materials can make the process prohibitive, not only for the small manufacturer but also for the larger manufacturer. If, in fact, DuPont has treated all manufacturers equally, then all implantable medical device manufacturers have only 1½ years to overcome this crucial gap in time. Meadox has already contacted more than 15 alternate suppliers worldwide. All were interested, initially, and they are willing to offer supplies for worldwide distribution—except in the United States. Their reason is always the same: The risk of liability is too high for the size of the market.

If, through the years, Meadox had been forced to have this level of concern on liability risk, I hate to think of how many people might not be alive today, or how many would have a poor quality of life because they would lack the products we did, in fact, develop. Constant dedication to a very small but specialized area of medical care has been our company's pride and creed. Included in this are the work and relationships with our suppliers that have helped us forge ahead into previously undiscovered areas of innovation. If we cannot preserve that spirit of innovation today, then time may well be running out for American surgeons and their patients.

PREPARED STATEMENT OF KATHERINE F. KNOX

Good morning. My name is Katherine F. Knox. I am a Business Program manager in Corporate New Business Development for the DuPont Company. For the last year I have been helping to coordinate implementation of DuPont's policy on use of materials in implantable medical devices.

DuPont is the nation's largest and oldest diversified chemical company. We are nearing the 200th anniversary of our founding on the banks of Delaware's Brandywine River, and that longevity is a direct result of our expertise in science and technology, especially in materials innovation and development. DuPont has been a leading manufacturer of many advanced materials such as DACRON® polyester fiber, TEFLON® ptfe resins, nylon fiber, LYCRA® spandex fiber, KEVLAR® aramid fiber, MYLAR® polyester film, TYVEK® spunbonded fabric, and numerous other materials. In general, DuPont does not make finished products, we make chemicals and raw materials such as fiber, film, or powder resin.

Many of these materials are found to be extremely useful by companies who make well-known consumer products. Examples include the use of DuPont materials under the SILVERSTONE® trademark for cookware, the use of KEVLAR® fibers in police protective jackets, or the use of NOMEX® fibers in fire fighters' protective clothing. Many materials are used extensively in specialized industrial applications.

Beginning in the 1940's researchers in medicine wanted to use advanced materials to develop implantable devices that would save lives, avoid more expensive therapies and relieve pain. Examples of such devices include sutures, vascular grafts to replace arteries, pacemakers, catheters and many other inventions.

DuPont's traditional business was supplying materials, not designing and manufacturing medical implants. DuPont knew that specialized industrial or consumer laboratory testing was not sufficient for medical implant applications. Clinical medical testing in hospitals and medical device expertise was required. DuPont was not a medical implant manufacturer with such facilities or expertise.

Therefore, in the 1950's DuPont adopted a conservative Medical Applications Policy which required medical researchers, medical implant manufacturers, hospitals,

or other medical persons to sign special terms and conditions of sale. DuPont informed all such customers that the DuPont materials were designed and manufactured for the requirements of the industrial and consumer markets for which they were intended or recommended for use by DuPont—not for implantation in the human body. DuPont further informed these customers that DuPont was not an implant manufacturer, did not seek or obtain FDA approval of medical devices made with our materials, and did not design or manufacture these materials for implantation in the human body. DuPont even required all such persons to sign a disclaimer stating that they would perform all necessary tests, medical and other, and obtain any necessary approvals from the Food and Drug Administration.

DuPont felt this was a reasonable Policy which avoided slowing or stopping medical advances. DuPont relied on the medical experts purchasing these materials to use them responsibly and the FDA to review the safety and efficacy of medical devices.

However, changes in legal trends and business since then have made it necessary for DuPont to adopt a new Policy. As of January 15, 1993, DuPont no longer supplies material to firms using these materials in permanently implantable devices, unless DuPont is involved in the design of the device itself. An example of the latter is the DePuy-DuPont Orthopedics venture.

The following is a description of some of the reasons for the new Policy.

Continuity of Process or Notice of Change

DuPont materials are high quality materials made to demanding standards. Thousands of customers buy these materials, and these customers help DuPont decide what is needed to meet the requirements of their applications.

Historically, DuPont has been reluctant to promise continuity of process or release specifications for most of the materials used by manufacturers in medical implants. The material which a medical implant manufacturer purchases is made with the same plant equipment, by the same process, and is the same grade of material used by DuPont customers in manufacturing industrial products and consumer products such as clothing.

DuPont materials conform to the needs of the intended industrial and consumer applications. Therefore, in many cases DuPont businesses, in practical terms, are not able to make a commitment to customers who make medical implants to (a) make no changes, or alternatively (b) report to the implant manufacturer all changes and improvements in plant, process, or release specifications. Furthermore, DuPont does not know what characteristics or process changes are significant to the medical implant application.

The small volume of material used in medical implants cannot support separate plant equipment, separate processes and separate release specifications necessary for materials designed to meet the special requirements of medical implants, and the cost of making small batches would be prohibitive.

Litigation is an Inherent Business Risk of the Medical Implant Field

Historically, DuPont has not designed, tested, manufactured, or sold the medical implants. In general, such medical devices provide high value to patients and are important, life-saving or life-extending products. In almost all cases, the quantity of raw material used to make a medical implant is minuscule. Only a few grams, or cents, of raw material may go into a medical implant. Even the total gross amount of raw material used in all implantable medical devices in the U.S. is believed to be relatively small.

Unfortunately, in America disappointment in medical treatment often results in lawsuits against any company even remotely connected with the medical product. In recent years there has been a growing trend to sue raw material suppliers. In general, implantable medical devices are the subject of voluminous and expensive product liability litigation. Implant manufacturers can spread such costs among implant recipients by building the cost into the price of the implant. Due to the small volume of material involved and due to the often indirect sale through distributors, raw material suppliers cannot pass these costs along to device manufacturers.

Generally, courts have found that raw material suppliers are not responsible finished medical implants. However, cases have to be defended at great cost to get to the point where a court determines that the company is not responsible. Litigation can involve hundreds or thousands of cases with each case generating thousands of dollars in lawyers' fees. This can translate into millions of dollars in defense costs, even when the company is only a raw material supplier.

For example, 5 cents of raw material can make one medical implant. Fifty dollars worth of raw material can make one thousand implants, which can generate one thousand lawsuits. Those lawsuits can generate millions of dollars in legal costs—even if the company is found to be faultless. It can cost a company millions of dol-

lars of lawyers' fees as a result of selling fifty dollars worth of material for use in the field of implants.

Most medical implant manufacturers in their entire history may never experience large scale litigation. They view the risk of catastrophic litigation as remote. Their risk is limited to their products, which they know and can manage.

Ironically, a raw material supplier who does not control the finished product can become involved in large scale litigation. There are few materials acceptable for use in the human body, and many medical implants may be made from the same small group of materials. This increases the odds that one of these few materials will be involved in a device in litigation.

A company selling raw materials cannot justify the millions of dollars in costs, the court appearances, and the press coverage which may accompany these controversies over medical implants.

Disappearance of Adequate "Occurrence Based" Insurance

The disappearance of adequate "occurrence based" insurance coverage in the United States is another reason why a raw material supplier can no longer afford to be associated with implantable medical devices. Historically, a company used to be able to buy insurance which covered it for current activities ("occurrences") which resulted in claims and lawsuits filed in the future. A company could rest assured that, if it bought insurance covering sales operations today, it could depend on insurance coverage for any claims 5, 10, or 15 years in the future.

That type of insurance is no longer generally available in the U.S. at affordable prices. Today most policies are "claims made" policies. These policies only cover a company for the lawsuits filed in the following year. They do not insure a company for claims or lawsuits which are filed in future years. If lawsuits are filed, the insurance carrier can refuse to renew the Policy for future years. Even the large companies can be left without any insurance.

This is a particular problem in the medical implant industry. The implant may remain in the body for as long as 20 years. This generates a long potential future "tail" of claims. A company cannot buy insurance in the current year (when the implants are sold), which will cover the potential future claims over the next 20 years. If claims start to accumulate, then the insurance carrier can refuse to renew the policy. There will be no insurance for the remaining years when the products are more likely to "wear out" and become obsolete and when insurance will be most needed.

Inability to Replace, Recall or Repair Implant Products

Inability to replace, recall, or repair medical implants is another unique problem. If a toaster, a refrigerator, or a car become damaged, or obsolete, after 20 years they can be replaced, recalled or repaired.

However, medical implants are expected to remain in the body and perform well sometimes for as long as 20 years. Obviously, medical implants are equally subject to the ravages of time and obsolescence. Medical implants are not easily replaced, recalled or repaired. It requires surgery to replace, recall or repair the medical implant.

Telling the medical implant patient that they must undergo risky, painful and expensive surgery (often not covered by medical insurance) for replacement, recall, or repair, is liable to make them into a bitter enemy and result in a lawsuit.

The Medical Community May No Longer Have the Deciding Voice

The medical community has tremendous value for the thousands of useful medical implants. For example, sutures are essential to all surgery. However, society has not always kept these benefits in mind when allocating responsibilities for the risks involved.

Currently, the litigation climate with respect to medical devices has become increasingly hostile to raw material suppliers. Since the medical community may no longer have the deciding vote on highly publicized medical issues, these risks have increased. The fact that the FDA approved the medical implant, and frequently a majority of the medical community supported the implant, carries little weight with the courts, the public, and the press. Companies associated with the medical implant can become the object of endless lawsuits, press coverage, and public disapproval.

DuPont is a company that stands behind the products we manufacture and sell. However, we do not manufacture or sell medical implants. A company whose only involvement with an implant is selling raw materials cannot justify involvement in these controversies over medical implants.

Conclusion

We at DuPont are saddened by the need to withhold our materials from use in permanent medical implants. It was not a decision we arrived at lightly. Since announcing the decision last year, we allowed a transition period for our customers to find alternate suppliers or materials, even though this meant assuming additional business risks. Unfortunately, the realities of the American litigation system no longer allow companies such as DuPont to supply small amounts of highly valued materials for use in implants without risking involvement in large scale implant litigation.

PREPARED STATEMENT OF JAMES S. BENSON

Mr. Chairman, my name is James S. Benson, and I am senior vice president for technology and regulatory affairs of the Health Industry Manufacturers Association (HIMA). HIMA is a national trade association representing more than 700 manufacturers of medical devices, diagnostic products, and health care information systems. HIMA's members manufacture more than 90 percent of the approximately $40 billion of health care technology products purchased annually in the United States.

I appreciate the opportunity to testify here today, Mr. Chairman, on a subject that is of potentially grave concern to our nation's public health—an impending shortage of the raw materials medical device manufacturers need to produce certain devices designed for implantation within the human body. The materials in question are used as biomaterials. Biomaterials, to put the concept simply, are materials that, because they are generally compatible with the human body, are used in medical devices placed in contact with internal tissue and fluids.

The biomaterials that these raw materials become when used in this fashion are an indispensable element in hundreds of life-saving and life-enhancing products, from pacemakers to surgical stitches. Without a reliable supply of those basic materials, the lives of thousands of patients may be in jeopardy. Equally important, without a reliable supply of materials, the innovation that produces these life-saving devices may come to a halt; already, many companies are backing away from engaging in research and development for new products that may require biomaterials.

The medical device industry is extremely grateful to you, Mr. Chairman, for holding this hearing so that this problem can be brought before this committee, the Congress, and the American people.

The Problem

Basically, the problem is this: In the current litigious environment in the United States, companies that supply to our industry the raw materials ultimately used as biomaterials are reluctant to continue doing so. They tell us that under existing legal procedures, they will be liable for potentially huge costs of litigation for products that account for a very small part of their sales. A supplier of a raw material may be brought into litigation even though the supplier has no direct role in the material's ultimate use as a biomaterial. And suppliers may spend millions of dollars defending lawsuits involving products that account for only a fraction of their total market.

There are those, Mr. Chairman, who would argue that suppliers ought to be held liable if a manufactured product using their materials causes injury. But suppose a car wrecks because its steering mechanism fails. Should the supplier who provided the steel to the car company be held accountable if the steel meets company specifications and the failure is the result of a faulty design decision by the car company? Shouldn't the supplier's responsibility to defend lawsuits be limited to situations where its wrongdoing led to the injury?

As a direct result of the liability environment in this country, three major raw materials suppliers recently announced that they would limit or cease altogether their shipments to medical device manufacturers. In all three instances, the companies stated that these were purely rational business decisions. To these companies, the cost of responding to litigation related to the affected product areas—even in frivolous lawsuits dismissed out of hand—were simply too high, far exceeding the relatively minuscule revenues generated from these materials. For example, the approximate total market value for DuPont's Dacron® polyester (PET yarn) is $9 billion. Yet the approximate value of the market for medical device usage of PET yarn is only $185,400.

When suppliers withhold materials because they fear the cost of litigation, the ability of some manufacturers, especially smaller companies with limited resources, to continue producing their life-saving products is threatened. And that, in turn,

poses problems for the public health, as thousands of Americans could be denied access to critical products for which there are, currently at least, no substitutes.

The Medical Device Industry

Before I discuss the history of this problem in more detail and offer some possible solutions, let me say a word about the medical device industry. First of all, device companies are innovative; they invest an average of 6.7 percent of sales in research and development, nearly double the 3.7 percent national average for manufacturing companies. Thee fruits of this investment are products that enhance the quality and value of patient care and increase the productivity of the U.S. health care system.

In the last 20 years alone, several innovative products have added immeasurably to the health and well-being of patients. Those products range from non-invasive diagnostic tools, which allow doctors to pinpoint a disease process with such astonishing accuracy that the frequency of "exploratory surgery" has been significantly reduced, to implantable devices such as pacemakers and defibrillators, which use the latest in microprocessing technology to assist malfunctioning hearts, and to lasers and other sophisticated devices that allow surgeons to remove affected tissue safely from even the most delicate areas of the human brain. These products may not all use biomaterials, but many life-sustaining ones, such as pacemakers and defibrillators, do.

Innovation by U.S. medical device manufacturers has made the U.S. industry the world leader. But our industry's global competitiveness is clearly at risk absent a steady supply of raw materials. The device industry is made up primarily of small, entrepreneurial companies, the majority of them employing fewer than 100 workers. These smaller companies account for the bulk of new innovations, and it is these companies that have helped make the industry one of our nation's most competitive.

More specifically, the medical technology industry is one of the fastest-growing manufacturing sectors in the United States. The Commerce Department reports that four of the top nine fastest-growing manufacturing industries of the U.S. economy from 1987–1994 are in medical device technology. This industry achievement is unprecedented in the history of Commerce Department tabulations. Our industry generated a $4.5 billion trade surplus last year, a figure that has grown steadily each year; more than a third of the industry's growth is in exports. Currently, U.S. based companies supply 46 percent of the world's medical devices.

And our industry has been adding people to the workforce at an average annual rate of nearly 4 percent. Today, some 280,000 men and women are employed in the medical technology industry throughout the United States.

In sum, then, the medical device industry is one of America's most competitive. That competitiveness—like the improved medical care that new technologies make possible—is very much at stake, Mr. Chairman, as we consider remedies to the shortage of biomaterials our companies face in the very near future.

History of the Problem

Let me offer a brief history of the problem. Within the last several years, we have witnessed an alarming and accelerating trend in which the three major suppliers of materials used in critical medical implants first have announced their intention to withdraw from the market, and then have followed through by either restricting sales or halting them altogether.

Dow Chemical, for example, has virtually stopped supplying its medical grade resin and film to the implant market, with one exception—apparently, polyurethane will be supplied only for limited use in pacemaker leads and related pacing devices, but only until April 30, 1995. With respect to silicone, in March 1993, it is our understanding that Dow Corning stopped supplying it for use in permanent medical implants (implanted for more than 30 days) and in all reproductive, contraceptive, obstetric, and cosmetic applications.

Finally, on January 31, 1994, DuPont ended a one-year grace period and discontinued its supply of materials—including PTFE (Teflon®), polyester (Dacron®), and polyacetal (Delrin®)—to the permanent medical implant industry. Supply for temporary implants (generally less than 30 days) are to be decided on a case by case basis. Other material suppliers have followed suit or are currently reviewing their policies regarding the market. Without such materials, it would be impossible for doctors to implant a host of very important devices, such as the "shunts" that drain excess fluid from the brains of children afflicted with hydrocephalus.

The polymers that have been withdrawn serve multiple functions in a range of medical devices, from being the primary device component (e.g., in shunts) to being simply electrical insulation (e.g., in pacemakers). Currently, material suppliers' policies primarily focus on permanent implants and temporary medical implants. However, future restrictions may be extended to any material which comes in contact, internally or externally, with a patient. In fact, there is the potential for a "snow-

ball" effect here, as more and more component suppliers withdraw from the medical implant market because they, too, fear liability costs.

For now, we believe we can say that, as a result of the reduced availability of biomaterials, it is likely that certain vital life-saving and life-enhancing medical devices will be unavailable to patients in the near future. And, it bears repeating, that these are merely the products we now have. The insidious danger, of course, is that the public may never know what new life-saving and life-enhancing products had to be sacrificed on the drawing board because biomaterials—the building blocks of many medical devices—were unavailable because of the practice of "defensive innovation." Defensive innovation happens when companies turn from the goal of advancing medical science because of the fear of or fallout from the litigation environment.

Market Study

The effects of a biomaterials shortage are confirmed in a market study conducted by Aronoff Associates (a copy of which is attached to this testimony), a consulting firm specializing in the use of polymers in health care products. The study focused on the three materials that have been withdrawn by DuPont from the permanent medical implant market: Dacron® polyester, Teflon® PTFE, and Delrin® polyacetal. HIMA commissioned the study to gain an understanding of the biomaterial market structure, the supply situation, and the future of the market. The study found that the combined size of the permanent medical implant markets for the three materials is minute ($600,000) compared with the total markets for those materials ($10.5 billion).

In many cases, there are no alternative suppliers of Dacron® polyester, Teflon® PTFE, or Delrin® polyacetal. Where alternative suppliers exist, those willing to consider supplying will insist on financially stringent indemnification agreements—costing millions of dollars—a condition that could literally put them out of reach for small companies, the engines of innovation in the medical technology industry. Unfortunately, for many materials, suitable replacements simply do not now exist. Some manufacturers may have stockpiled approximately a 3-year supply of DuPont materials, many others have less. The study concludes that these findings can be applied to all materials used in medical implants.

Aronoff Associates offer some starting forecasts. Over the short term (1–3 years), the financial requirements needed to back indemnification agreements will begin to force small manufacturers and start-ups out of business. U.S. manufacturers will have to divert resources from research and development to search for and qualify replacement materials. That is already happening for many companies.

Assuming manufacturers' reserves of the DuPont materials do not deteriorate, a DuPont materials shortage will not be felt by patients in the short term. However, they will surely feel the shortage in the long term. Over the next 3 to 10 years, Monoff Associates estimate, the full effect of the biomaterials crisis will be felt—unless substitute materials are found and approved for marketing. This means, quite simply, that patients will not have access to life-saving, life-enhancing medical implants if suitable replacements are not available. Unique, "tried and true" study materials will, in all likelihood, disappear completely, with profoundly damaging consequences for small manufacturers and the innovations they typically spawn.

Impact of a Shortage

Manufacturers cannot produce implants if the appropriate raw materials are not available, and, as reported in the Aronoff market study, materials may not be available for three primary reasons. First, as I have mentioned above, the fear of litigation may prevent existing and potential material suppliers from participating in the implant market. Second, suitable replacements for the materials withdrawn may simply not exist. And third, even if replacement materials are found, it may be several years before they can be used because approval for their use in existing implants may be further delayed due to FDA requirements for long-term testing.

I know there are those who believe that consumer protection only means protecting consumers from unsafe products—and that is certainly an important aspect of this issue that we fully support. But too often we overlook another important aspect of consumer protection, and that is, that consumers are also protected when companies bring forward new products that attack disease, that make people healthier, that sometimes save their lives. As a federally appointed blue ribbon panel reviewing the Food and Drug Administration (FDA) said, "The FDA must recognize that approval of useful and safe new products can be as important to the public health as preventing the marketing of harmful or ineffective products." The panel concluded that we can "strengthen the competitive nature of American innovation without . . . compromising consumer protection."

There are also those who would argue that, because some manufacturers may have experienced problems with a particular material, the use of all biomaterials should be questioned. That argument misses the point entirely. First, if there is a problem, it is not with the biomaterials themselves, which, in general, are inherently safe, but rather with the way in which they may have been inappropriately applied. Second, the proper use of those biomaterials has made possible devices that have saved thousands of lives. Let me mention a few of those products and what they make possible:

Heart valves. Heart valves are used to control the flow of blood between chambers in the heart. Mechanical and tissue heart valves replace damaged or missing valves in patients. When a damaged valve leaks, a backwash of blood flows from the bottom chamber (ventricle) to the top chamber (atrium) during the heart's ventricular contraction. This causes the heart to function inefficiently and, in severe cases, leaves the heart unable to circulate blood. Without replacement heart valves, patients would suffer improper blood flow, premature heart fatigue, or death.

Pledgets. Pledgets are a common tool surgeons use in a variety of surgical procedures. Pledgets buttress fragile tissue and are a staple in cardiovascular-related operations. In addition, they serve to reinforce sutures or soft tissue and prevent leaking in numerous other applications. Without pledgets, physicians would find it more difficult to perform a range of surgeries, from basic operations to heart bypass surgery.

Vascular grafts. Vascular grafts are used to repair or replace arteries in people whose own arteries have become dilated or injured. Many vascular grafts are "tubes" made of synthetic material(s). For example, a polyester vascular graft can be used to treat a dilated aorta (aneurysm). Left untreated, the aneurysm will rupture, and the majority of these patients will die. The use of polyester grafts has reduced dramatically the death rate from ruptured aneurysms.

Vascular grafts are also used to replace blocked major arteries. If the blocked artery is not replaced, the patient often suffers from gangrene and infection of limbs, which can lead to amputation and, in some cases, death. Short grafts are used to replace blocked arteries to the kidneys. Similar grafts are used as shunts in infants who have inherited heart defects. Approximately 330,000 vascular grafts were implanted in 1991–92.

Hydrocephalus shunts. Hydrocephalus is a very serious condition for which there is no cure. The condition occurs in approximately one of every four hundred live births, or can be triggered by disease, infection, tumor encroachment, traumatic injury to the head, or aging. A build up of cerebrospinal fluid in the brain causes an increase in pressure within the skull. Untreated, hydrocephalus can lead to stunted mental and physical development, coma, or premature death.

Hydrocephalus can be managed through shunting or moving the fluid from the brain to another location in the body, where it can be absorbed. There is no alternative therapy, drug, or device regimen, and the condition requires lifelong treatment. The hydrocephalus shunt is fully implanted and, typically, will function for many years. With regular follow-up care, modern hydrocephalus shunts are well tolerated and allow patients to lead normal and complete lives. About 75,000 shunts are implanted annually.

Other devices that might be affected by a biomaterials shortage include sutures used on internal tissues, heart valves, and penile implants. Even more important, though, than the fact that the device may be unavailable is what that means for the practice of medicine and for the patient. Because devices are the tools through which millions of medical procedures are performed—procedures which are performed for the ultimate benefit of patients—the reduced availability of biomaterials means the reduced ability to receive adequate health care for literally millions of patients from infants to the elderly. To help grasp the sobering impact of a biomaterials shortage on patients and medical procedures, I have attached a chart which shows just how particular devices, procedures and patients are linked.

A biomaterials shortage could also have severe economic ramifications—perhaps as soon as a year from now. Many device manufacturers, especially small companies, could be forced either to cut back significantly on their operations, or, conceivably, forced out of the medical implant business entirely. Under either scenario, the economy would suffer, both locally and nationally as the job losses across the country accumulate. That, in turn, would undoubtedly deliver a severe blow to our industry's innovative capabilities and limit the variety of medical products available in the future. And, if industry innovation suffers, a vibrant segment of our national

economy, one of the few, in which we demonstrate clear global leadership, will regrettably diminish.

One possible result is that the medical implant industry will move their operations overseas, a trend that, for a variety of reasons, is already taking place today. In the absence of U.S. suppliers, U.S. medical device manufacturers will be forced to seek raw material suppliers elsewhere. They will also be driven to develop and introduce their products overseas due to the litigious U.S. environment. Ironically, the best U.S. medical products might then be available only to patients in foreign lands. Moreover, in an industry currently dominated by the United States, the global competitiveness of U.S. companies could be jeopardized.

Along these lines, HIMA would also like to go on record in support of S.687, "The Product Liability Fairness Act," which, if enacted, would certainly improve the climate for innovation in medical technology and encourage companies to continue to export U.S. products, not U.S. jobs.

Work on the Issue

The Health Industry Manufacturers Association has been engaged in several efforts to ensure that patients continue to have access to critical medical devices. HIMA has already worked with the FDA, manufacturers, scientists, and chemical companies to explore ways in which alternative supplies of silicone could be used to keep existing products on the market. In particular, HIMA has assisted FDA in establishing a testing regimen to demonstrate the equivalence of the silicone available from alternative suppliers who step forward with a substitute to Dow's silicone.

Unfortunately, however, because the risk of liability still exists, the current supply situation for silicone should be considered fragile at best, especially since the two companies that have so far stepped forward as alternative suppliers are small. Although the silicone resolution might be used as a model for other materials, that process will be much more difficult because "equivalent" materials are less abundant and may not even exist for these other materials. There is, in short, no guarantee that companies will be able to find alternate suppliers for the polymers that have been withdrawn.

HIMA is part of the Biomaterials Availability Coalition (BAC), which was formed to help avert a biomaterials crisis. The BAC comprises medical societies and scientific organizations and is working to educate the medical community, Congress, and the general public on the impact of a biomaterials shortage on the delivery of patient care. The BAC founding member organizations include the American Academy of Ophthalmology, the American Academy of Orthopedic Surgeons, the American Association of Neurological Surgeons, the American College of Cardiology, the Joint Vascular Societies, the American College of Obstetricians and Gynecologists, the American Society of Plastic and Reconstructive Surgeons, the American Urological Association, the Society for Biomaterials, the Society of Thoracic Surgeons, and the American Society for Artificial Internal Organs.

Conclusion

In conclusion, Mr. Chairman, the public health of thousands, maybe millions of patients and the economic health of our Nation will likely be adversely affected by a biomaterials shortage. HIMA believes a solution requires immediate congressional attention, in order to provide continued patient access to life-saving, life-enhancing implantable medical devices. We believe this hearing is an important first step in that process.

The medical device industry, the FDA, and others are all working to find solutions to this potential crisis. HIMA believes, however, that the only way to avert a biomaterials crisis is timely legislation that limits supplier liability to instances of genuine fault and establishes a procedure ensuring that raw materials suppliers will not be brought into litigation unless there is good reason to believe they are, in fact, at fault. The impact of this approach will be that manufacturers ordinarily appear in lawsuits on behalf of suppliers, thus relieving the suppliers of heavy legal defense costs. Device manufacturers are willing to assume this burden as a way to help ensure the continued availability of the materials they need to make their products, products that American patients so desperately need.

HIMA appreciates your interest in this matter, Mr. Chairman, and we would be happy to work with the Subcommittee in any way we can to find a workable solution. Thank you.

MEDICAL PROCEDURES/PATIENTS AFFECTED BY A BIOMATERIALS SHORTAGE

MEDICAL SPECIALTY	AFFECTED PROCEDURE	NUMBER OF PROCEDURES/ PATIENTS (Annually)	AFFECTED DEVICE
CARDIOLOGY & THORACIC SURGERY	Angioplasty	331,000	angioplasty catheter +
Source: American College of Cardiology	Diagnostic Cardiac Catheterization	1,057,000	cardiac catheter +
& Society of Thoracic Surgeons	Implantable Cardiac Defibrillator	35,000	cardiac defibrillators
	Open Heart Surgery	342,600	blood filters +
			cardiotomy reservoir +
			heart/lung oxygenator +
	Pacemaker Implantation	140,000	pacemakers
	Valve Implantation	35,000	mechanical valves
			tissue valves
			annuloplasty rings
	Vascular Graft Related	330,000	polyester grafts
			other grafts
Number of Patients Affected:		2,270,600	

MEDICAL SPECIALTY	AFFECTED PROCEDURE	NUMBER OF PROCEDURES/ PATIENTS (Annually)	AFFECTED DEVICE
ORTHOPEDICS	Arthroplasty	617,000	hand and finger prothesis
Source: American Academy of Orthopedic Surgeons			hip prothesis
			knee prothesis
			shoulder joint orthopedic
	Other Orthopedic Related	data not available	bone growth stimulator
			fracture fixation device
Number of Patients Affected:		617,000	
OPHTHALMOLOGY	Cataract Surgery	1,500,000	phacoemulsification unit +
Source: American Academy of Ophthalmology			foldable silicone intraocular lens
	Glaucoma Shunts	3,000	eye valve implants
	Punctum Plug Related	data not available	silicone punctum plug

MEDICAL SPECIALTY	AFFECTED PROCEDURE	NUMBER OF PROCEDURES/ PATIENTS (Annually)	AFFECTED DEVICE
OPHTHALMOLOGY (con't)	Scleral Buckling for Retinal Detachment	25,000	absorbable implants
			silicone sponge
			solid silicone strips
			cryoophthalmic units +
	Silicone Oil Related	data not available	silicone oil +
	Temporary Scleral Buckle	700	balloon catheter +
	Vitrectomies	53,000	vitreous cutting device +
	Other Ophthalmic	data not available	extraocular orbital implant
			intracorneal implant
			rigid gas permeable contacts +
			scleral plug
Number of Patients Affected:		1,581,700	

MEDICAL SPECIALTY	AFFECTED PROCEDURE	NUMBER OF PROCEDURES/ PATIENTS (Annually)	AFFECTED DEVICE
NEUROLOGY	Ventricular Shunt	75,000	CNS shunt
Source: American Association of Neurological Surgeons			
Number of Patients Affected:		75,000	
UROLOGY	Anti-incontinence Operations	2,500	urinary sphincters
Source: American Urological Association	Diagnostic Ureteroscopy / Cystoscopy	500,000	endourology devices +
	Laser Prostetectomy	250,000	laser fibers +
	Multiple Urological	100,000	suction drains +
	Penile Prosthesis Procedure	50,000	penile prostheses
	Prostetectomy / Reconstructive	250,000	silicone urinary catheter +
	Multiple Urological & Other	1,000,000	ureteral catheter/stents +
	Stone Manipulation	500,000	basket graspers +
	Testicular Prothesis Procedure	1,000	testicular prostheses
Number of Patients Affected:		2,653,500	

MEDICAL SPECIALTY	AFFECTED PROCEDURE	NUMBER OF PROCEDURES/ PATIENTS (Annually)	AFFECTED DEVICE
RECONSTRUCTIVE SURGERY	Breast Augmentation	29,607	saline-filled breast implant
Source:			silicone gel-filled breast implant
American Society of Plastic & Reconstructive Surgeons	Breast Lift	7,963	saline-filled breast implant
			silicone gel-filled breast implant
	Breast Reconstruction	32,607	saline-filled breast implant
			silicone gel-filled breast implant
	Other Reconstructive/Plastic Surgery	data not available	cheek implants
			chin implants
			tissue expanders

MEDICAL SPECIALTY	AFFECTED PROCEDURE	NUMBER OF PROCEDURES/ PATIENTS (Annually)	AFFECTED DEVICE
RECONSTRUCTIVE SURGERY (con't)	Hand Surgery	*138,233	no device data available
Number of Patients Affected:		208,410	
TOTAL NUMBER OF PATIENTS IMPACTED BY A			
BIOMATERIALS SHORTAGE:		7,406,210	

April 1994

* *The total number of hand surgeries is listed; however the percentage of these which will be affected is still uncertain.*

\+ *At this time, the impact of a biomaterials shortage on (or the unavailability of) temporary implants or devices which temporarily come in contact with the body is not as certain as that on permanent implants.*

Note:
Estimates compiled from Medicare/Medicaid records, federal records (where available), and input from physicians, manufacturers, and regulatory representatives. Current private sector statistics are generally not tracked and are difficult to obtain. Figures may be understated.

Aronoff Associates

Market Study

Biomaterials Supply for Permanent Medical Implants

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March 1994

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EXECUTIVE SUMMARY

Background

Prompted by the withdrawal of E. I. du Pont de Nemours and Co. (DuPont) as a supplier of key materials to permanent medical implant manufacturers, HIMA commissioned this study to develop an understanding, from the perspective of the materials supplier, of the principal factors that operate in this market. The scope of the study was limited to three materials: polyethylene terephthalate (PET) yarn, polytetrafluoroethylene (PTFE) fiber and resin, and polyacetal resin. All three are supplied by DuPont under the registered trade marks "Dacron®," "Teflon®," and "Delrin®," respectively.

Objectives of the Study

The major objectives of the study were to:

A) Provide information on the size and structure of the United States market for polyethylene terephthalate, polytetrafluoroethylene, and polyacetal used as biomaterials for permanent medical implants.

B) Identify and analyze, from the material supplier's perspective, the key factors that govern the current and potential supply of materials to manufacturers of permanent medical implants.

C) Develop short term and long term forecasts indicating the pattern and adequacy of the raw material supply for permanent medical implants and possible consequences thereof.

D) Identify alternate and potential suppliers of equivalent, replacement materials for Dacron®, Teflon®, and Delrin®.

Findings

Size of Market for Materials Used in Permanent Medical Implants - Estimated quantities of subject raw materials consumed in making permanent medical implants were generally derived from the number of different implant units sold annually to United States hospitals as reported in a commercial database. Total consumption by the United States implant industry in weight and dollar volume for each material was calculated by applying factors to account for exports, manufacturing losses, and other contributing elements.

Principal findings are:

1) Dollar values of the permanent medical implant markets for PET yarn, PTFE fiber and resin, and polyacetal resin are a minute fraction, even at ten times our estimates, of their values for their other markets (*e.g.*, automotive, electrical, or textile markets).

2) The implant market value is clearly not commensurate with the liability risk. For example, it can be estimated DuPont spent about $8 million annually (for the past 5-6 years, based on an estimate of their out-of-pocket costs) for its defense of cases arising from the use of Teflon® PTFE in a temporo mandibular joint (TMJ) implant.

3) The majority of these materials consumed by this market are used in the production of lifesaving, permanent medical implants [*e.g.*, vital blood vessel replacements made from knitted polyester (PET)]. The remainder is used in life-enhancing, permanent implants [*e.g.*, hernia patches made of polyester (PET) fabric].

These findings are summarized in the following table:

	Approximate $ Value for Implants	% of Other Markets	% Life-saving	Approximate $ Value Total Other Markets
PET Yarn	185,400	0.002	80	9 Billion
PTFE Fiber	261,000	0.3	75	90 Million
Resin	157,000	0.08	85	192 Million
Polyacetal Resin	3,300	0.00025	100	1.3 Billion

Supply - DuPont has probably been the sole source of polyester (PET) yarn and PTFE fiber for the United States permanent medical implant industry. It has been a supplier, but probably not the major one, of PTFE resin used in vascular grafts. DuPont and Hoechst Celanese have both supplied polyacetal to the implant industry.

Reserves of subject materials have been built up through normal purchasing patterns and through purchases made from DuPont during a "grace period." Up to January 31, 1994, DuPont continued to supply subject materials to certain manufacturers based on the manufacturer's purchasing history with DuPont. Decisions to supply were made on a case by case basis. These reserves of FDA-

qualified materials will allow at least some manufactures to maintain production for about three years. However, in some cases, reserves may be exhausted sooner.

Most other companies producing the subject materials are now unwilling to even consider supplying United States permanent medical implant manufacturers. Currently, only one company, Wellman, has committed to supplying this market. They will sell polyester (PET) yarn only under stringent indemnification agreements. Manufacturers must be able to rigorously demonstrate, to Wellman's satisfaction, that they have the financial ability to honor such agreements. A few other potential suppliers have expressed interest in indemnification agreements as the first step in considering sales to implant manufacturers.

Factors Influencing The Decision To Supply Medical Implant Manufacturers - The most important factor today from the perspective of the raw material supplier, in the decision to supply (or not supply) the implant industry, is the fear of exposure to costly, possibly catastrophic lawsuits in an extremely litigious area. This, coupled with the fact that the dollar value of the permanent medical implant market is virtually imperceptible relative to other markets, has created a situation in which most suppliers are not interested in selling to the market. At present, most companies, willing to consider supplying the market, would do so only under the protection of solidly backed indemnification agreements. However, even then, there are reservations as their materials were generally never intended for implants. The motivation for supplying the implant market appears to stem from a feeling that medical needs, particularly when they are associated with saving or improving lives, are in a special category and should be met.

Forecasts

Short Term Shortages - In the short term (1 - 3 years), today's uncertain raw materials supply remains an everyday fact of life for the medical industry. Assuming no catastrophe destroys existing manufacturers' reserves of FDA-qualified subject materials, and that they do not deteriorate (*e.g.*, PET yarn), the uncertain supply situation will probably have little to no effect on patients or their doctors, as most medical implant manufacturers continue to produce from these reserves.

Long Term Shortages - In the longer term (probably after three years), a crisis looms in which patients and doctors may be affected by shortages of vital medical implants and the disappearance of certain unique, well-established, reliable materials used in critical surgery. Surgeons will have to contend with the loss of familiar products such as PTFE surgical felts, often used in coronary valve replacement surgery, and may be forced to use less reliable substitutes on their patients. More significantly, implant shortages will develop as reserves of subject materials used in FDA approved implants are exhausted, if implants made with replacement materials are not yet FDA approved. Long term FDA testing requirements, delays in finding and qualifying substitutes, and difficulties in adjusting manufacturers' processes to the new materials may stall the use of replacement materials.

Furthermore, new suppliers may withdraw at any time due to increased liability fears, thereby forcing the entire process to start over.

Industry Competitiveness - In both the shorter and longer terms, the supply of raw materials to the industry will remain in turmoil, forcing diversion of resources and money to find and secure replacement materials in order to support current product lines while slowing research and development leading to new products.

Indemnification agreements with stringent conditions and safeguards, which only financially powerful companies can meet, will be imposed as a precondition to supply. In the longer term, the financial requirements needed to back indemnification agreements for material supply will alter the structure of the implant industry itself, causing the demise or acquisition of a highly innovative segment: small companies and independent start-ups.

Furthermore, raw material supply will be obtained, where possible, from offshore suppliers, with insignificant United States assets, against whom United States judgements would be almost unenforceable. Such suppliers may be willing to sell to United States implant manufacturers and may not require indemnification.

In contrast, foreign medical implant manufacturers will have an easier time obtaining replacement materials from foreign suppliers, as sales to these manufacturers (often made indirectly) are apparently not considered as risky as sales to their United States counterparts. In the longer term, while United States manufacturers will have to find and qualify replacement materials continuously, their foreign competitors will be able to focus on development and production of new and improved medical products. Eventually this, along with the demise of innovative small companies, will lead to the loss of United States industry leadership in the medical implant field.

INTRODUCTION

In a letter to its customers dated January 15, 1993, DuPont announced it was halting supply of materials to permanent implant manufacturers and would:

> "...phase out sale of materials to customers using our materials in medical articles intended for **permanent implantation** [original emphasis] in the human body or in permanent contact with internal body fluids or tissues."

This withdrawal was to be completed "...no later than January 31, 1994." (See Appendix A.)

DuPont alluded to "...unpredictable and excessive costs of doing business with manufacturers of **implantable** [original emphasis] medical devices..." According to knowledgeable sources the sale of about $0.05 worth of PTFE "Teflon" per temporo-mandibular joint (TMJ) implant to the now defunct Vitek, resulted in mass litigation against DuPont and eventually provoked it to withdraw from supplying the permanent implant industry.

Prompted by DuPont's withdrawal, HIMA commissioned this study to develop an understanding, from the perspective of the materials supplier, of the key factors that operate in the permanent medical implant materials market. In order to obtain a meaningful study in a timely manner, the scope of this study was limited to three materials: polyethylene terephthalate yarn (PET), polytetrafluoroethylene (PTFE), and polyacetal. All three are supplied by DuPont under the registered trademarks Dacron®, Teflon®, and Delrin®, respectively.

The major objectives of the study were to:

A) Provide basic information on the size and structure of the United States market for polyethylene terephthalate yarn (PET), polytetrafluoroethylene (PTFE), and polyacetal used as biomaterials for permanent medical implants.

B) Identify and analyze, from the material supplier's perspective, the key factors that govern current and potential supply of materials to manufacturers of permanent medical implants.

C) Develop short term and long term forecasts indicating the pattern and adequacy of biomaterial supply for permanent medical implants and their possible consequences.

D) Identify alternate and potential suppliers of equivalent replacement materials for Dacron®, Teflon®, and Delrin®.

Although confined to three polymeric materials, we believe this study accurately depicts the factors now generally affecting the supply of most materials to the medical implant industry.

I.

ESTIMATED ANNUAL CONSUMPTION OF SELECTED MATERIALS BY THE UNITED STATES PERMANENT IMPLANT INDUSTRY AND MARKET SIZE RELATIVE TO OTHER MARKETS

Methodology

Database - To estimate the annual industry consumption of each subject raw material, we have focussed on implants that are known to contain significant amounts of any of them and are sold in relatively large numbers. We determined the number of units of each such implant using publicly available data on annual sales to United States hospitals and then applied factors to estimate gross annual production and raw material consumption. As implantable items are not tracked separately by United States Department of Commerce statistics, a commercial source of information, the IMS America Hospital Supply Index database was used.

IMS tracks sales of pharmaceuticals and hospital supplies to a statistically representative sampling of United States hospitals by monitoring invoices on a quarterly basis. It is well regarded and extensively used by the health care industry for competitive purposes.

Tracking Raw Material Type - The IMS Hospital Supply Index database is especially useful for this type of study as it reports the number of units of items sold by companies as well as dollar volume. In addition, the items of interest for this study are often identified by material, *e.g.*, Dacron®, and non-Dacron®, for vascular grafts, Dacron®, sutures, and Dacron®, (or "velours," a type of PET fabric) or Teflon®, for surgical fabrics, meshes and patches.

As the database provides excellent breakdown of products by company, it is further possible to pinpoint items that use the materials of interest to this study since at this time there is clear demarkation of material by producing company: *e.g.*, the companies that make vascular grafts from expanded PTFE and those that use PET are distinct. In addition, a Frost & Sullivan study on "Soft Tissue Implants," published April 1993, identifies manufacturer with material type for the major market segment of vascular grafts. Where there was any doubt about the composition of an item, the manufacturer was contacted for clarification.

Corrections and Factors - The IMS database excludes federal and VA hospitals from its statistical sample of approximately 350 hospitals due to their different purchasing patterns compared to state, local and private hospitals. This sample is projected by IMS to the universe of 5,375 state, local and private hospitals. However, since units of implants are purchased and used at federal and VA hospitals, totals from the IMS universe were multiplied by a "hospital correction" of 1.06 to account for this omission. This is based on a 1992 total of 5,672 hospitals, including 168 federal and 129 VA hospitals, according to the American Hospital Association Annual Survey of Hospitals (*i.e.*, about 1.06 x 5,375). A description of the IMS hospital sample and methodology, provided by IMS, is given in Appendix B.

Worldwide exports, that account for about 50% of this industry's production, are also not included in the IMS database. Total United States units were therefore multiplied by 2 to correct for this.

For each type of implant, a typical weight was used to calculate the total weight of all units made from a raw material. Typical weights were estimated by averaging figures provided by individual manufacturers about their own products and by using dimensions provided in the product descriptions of the IMS database and material densities obtained from manufacturers and other sources.

As all manufacturing processes have losses and the stringent quality control of this industry produces further losses, it was necessary to multiply the weight of raw material by a "loss factor" to determine the amount of raw material originally used. Loss factors were based on an average of information provided by manufacturers and experts familiar with the processes involved.

As only sales to hospitals are given in the IMS database, goods made on an OEM basis for other manufacturers that are incorporated as a piece of another device are not picked up directly. An example of this is the use of tiny amounts of polyester for backings and collars to attach implants to tissue and annuloplasty rings used to repair heart valves. To account for this segment, the total quantity of raw material has been multiplied by an "OEM factor" estimated from industry information.

Calculations are based on 1992 statistics, the last year for which complete figures were available at the time the study was undertaken.

Polyester (PET) Yarn

Background - Polyester yarn has been used for permanent implants since the 1950's. It is considered a highly reliable, safe material used as a standard building block by permanent implant manufacturers. As a knitted or woven fabric it is used almost exclusively in wide diameter vascular grafts and competes with expanded PTFE in smaller diameter grafts. It has been standard practice to incorporate tiny amounts of polyester fabric in the form of collars, cuffs or backings as part of virtually every type of implant to enable suturing to the body. In most cases the sutures themselves have also been polyester. For all of these applications the United States industry has, over the years, relied virtually exclusively on several types of DuPont's Dacron® polyester. Indeed until recently the industry used Dacron® to describe virtually all materials made from polyester yarn. Major permanent implant uses of polyester yarn are given in Table 1.

TABLE 1 - POLYESTER (PET) YARN IMPLANT APPLICATIONS

Vascular graft prostheses

Annuloplasty rings (heart valve repair)

Fixation devices for tissue:
- sewing collar for heart valves
- attachment backing for implants
- central venous catheter cuff

Fabric and mesh patches used as supporting matrix in repair of:
- heart
- arteries
- hernia
- bladder
- other internal soft tissue

Artificial ligaments

Sutures

Reinforcing fabric for polyurethanes and elastomer sheets used in implants

Quantities of Polyester Yarn Consumed By Permanent Implants - Viewed from a textile perspective the industry consumes PET yarn to produce two major classes of products: a) specialized fabrics that take the form of vascular grafts, covers for biological vascular grafts, as well as patches and meshes for tissue reinforcement and as a means of attachment to tissue and b) braided structures, which almost exclusively take the form of sutures, a highly sophisticated form of sewing thread. Continuous filament polyester (T-56 and about 5 other types of Dacron®) has been used almost exclusively in these products. Negligible amounts of polyester staple (short fiber lengths as in cotton) are used to make tiny (by this industry's standards) amounts of surgical felt. These segments are most conveniently dealt with separately, although their total will account for virtually all PET yarn that may be permanently implanted.

Specialized Fabrics - IMS statistical data for the number of different polyester (Dacron®) vascular graft units were totaled and multiplied by the following factors to generate total units sold worldwide:

Federal and VA Hospital Correction	1.06
OEM Factor	1.1
Export Factor	2.0

Information supplied by manufacturers on the weights of the most representative straight and bifurcated grafts was averaged to arrive at a typical unit weight. The number of worldwide units multiplied by typical unit weight gave the total weight of units sold in 1992. As with any manufacturing process there will be some loss at each stage of production so that the final weight of product represents some fraction of the amount initially used. Overall loss factors between 2 and 3 have been cited by experts familiar with the processes involved. That is, the weight of product sold is about 1/3 - 1/2 of the weight of raw material used. A factor of 3 was chosen on the basis of a worst case scenario for loss.

A similar approach was applied to calculating the amount of PET used in making patches and meshes. Here, however, a range of unit weights was used. They were based on weights of specific items of known dimensions, obtained from manufacturers and estimated for similar items of known dimensions using fabric density (*i.e.*, fabric weight per unit area). Totals for this segment are given in Table 2.

TABLE 2 - PET YARN CONSUMPTION IMPLANTS 1992

USE	United States UNITS (IMS) 000	WORLD-WIDE UNITS 000	TYPICAL UNIT WEIGHT gm	TOTAL WEIGHT UNITS SOLD kg	TOTAL WEIGHT UNITS SOLD lb	MANUFAC-TURING LOSS FACTOR	TOTAL WEIGHT CON-SUMED lb	TOTAL $ PET @ $6/lb
Vascular Grafts	80.1	186.8	13.3	2,484	5,465	3	16,397	98,380
Fabrics, Patches, Mesh	24.1	56.2	4 - 19	421	926	3	2,779	16,672
TOTAL VG&F							19,176	115,052
Sutures	12,563	26,633	0.1	2,663	5,859	2	11,718	70,303
TOTAL VG&F + SUTURES							30,894	185,355

Sutures - A vast number of polyester suture items are listed in the IMS database under the category of Dacron® sutures. Although these sutures are widely used where a non-absorbable product is needed or preferred, not all of them will remain permanently implanted in the body. The following types of coated and uncoated sutures, that comprise the majority of units bought by hospitals and that are likely to be used in operations where parts of them will remain permanently implanted were included in the study:

Cardiovascular
Orthopedic
Gastrointestinal
General Closure
Urological
Non-needled precut

Of these types, sutures used in cardiovascular procedures are most likely to remain permanently implanted. Although not as true for the other types, they too were treated as permanent implants in this study. As sutures are used everywhere that a surgical procedure may be performed, from dentists' offices to hospital operating rooms, our tracking method will not give the true total number of units since only hospital purchases are counted. However, as procedures in which sutures become permanent implants are most likely to be done in hospitals, our method accounts for the number of units most relevant to this study.

Based on information supplied by industry sources, a loss factor of 2 and a typical unit weight of 0.1g were used. The OEM factor was put at 1 and the export factor remained at 2 for these estimates. The results are summarized in Table 2 which also gives an overall industry total for the quantity of PET consumed for implants and the value of the market.

Comparison With Other Markets - Total worldwide consumption of PET fiber was an estimated 20 billion pounds in 1991, according to SRI International (Chemical Economics Handbook). Approximately half of this was continuous filament yarn and monofilament for apparel, household and industrial uses. Considering only this segment, which includes the types of yarns used by implant manufacturers, and applying an average volume price of $0.90/lb for standard yarns, this market had a value of $9 billion. At about $6/lb (the average of current DuPont prices for the types of yarns used for implants) total implant consumption, including sutures, amounts to about $185,355 or only 0.002% of the world market.

Indeed even the amount of waste grade fiber consumed in the United States (133 million pounds in 1992) is an incredible mammoth compared to the poundage consumed by this industry annually.

Although we do not know the amount DuPont has spent annually in the last 5-6 years to defend itself against lawsuits arising from Vitek's use of PTFE Teflon® in a TMJ implant, informed sources suggest it can be very conservatively estimated by assuming legal fees for each case cost about $8,000 per year. As about 1,000 cases per year have been defended, this estimate amounts to $8,000,000 per year for lawsuit defense. We have taken this figure as a yardstick of risk against which to measure return, although the amount lawsuits might cost a company cannot be predicted. Compared to settlements against manufacturers of implants (*e.g.*, breast implants), this may be considered a very conservative estimate of risk. Nevertheless, even against this measure, the total annual PET implant market amounts to 2.3% of the lawsuit dollar risk.

Even at ten times its size, the implant market is inconsequential compared to other markets and this measure of risk. These observations are summarized graphically in Fig. 1. Please note that in Fig. 1, the bar for the "other" market represents only $50 million of a $9 billion total and on the same scale would be 180 times longer than the segment shown.

"Lifesaving and Life-Enhancing Implant Market" - Of the minuscule amount of polyester consumed by the permanent implant industry, how much of it goes to saving lives as opposed to enhancing lives? The analysis given in Table 3 attempts to answer this question.

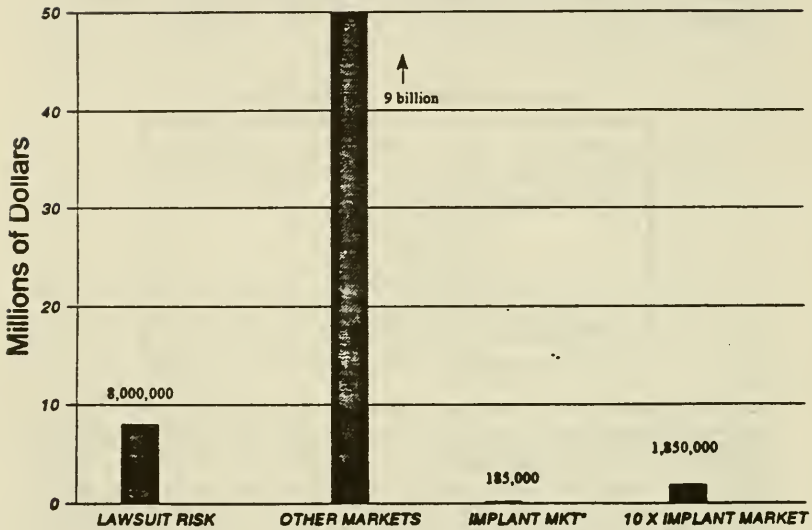
TABLE 3 - PET CONSUMPTION FOR LIFESAVING IMPLANTS

IMPLANT TYPE	USES	% LIFESAVING
Vascular Grafts	Blood vessel replacement	100
Patches, Meshes, Fabrics	Heart valve sewing ring, stent covers, annuloplasty rings, heart patches, central venous catheter cuffs, hernia patches, attachment cosmetic implants	50
Sutures (hospital segment)	Cardiovascular, general closure, orthopedic, others	60
ALL	ALL	80

Based only on vascular grafts and cardiovascular sutures, almost 70% of the total weight of PET consumed is certain to go towards production of lifesaving implants. When other fabric types such as sewing rings for heart valves, annuloplasty rings, heart patches and fabric cuffs on central venous catheters for long term administration of anti-cancer therapy and other suture types such as general closure are considered the total will rise further. In the absence of better data we roughly estimate that about 50% of the "fabric, mesh and patch segment" and about 60% of the suture segment included in this survey may also be considered lifesaving implants. On a weight basis about 80% of PET yarn consumed by the industry goes to lifesaving purposes. It should be noted that these percentages are not firm as this sort of information is difficult to pinpoint.

Major United States and Foreign Suppliers of PET for Permanent Implants - As may be surmised by perusal of the list of product classes for the IMS Hospital Supply Index database, any implant made of polyester yarn has used DuPont's Dacron®. That DuPont was virtually the sole supplier of PET to the United States permanent implant industry until very recently was confirmed

Fig. 1: PET YARN MARKETS VS. RISK



* *Vascular Grafts, Surgical Fabrics, and Sutures*

in interviews with knowledgeable industry sources. Practically all manufacturers obtained their PET supplies directly from DuPont, although in a few cases distributors or throwsters (*i.e.*, "texturizers") were apparently the immediate source.

The situation was apparently different in Europe where Enka of the Akzo group has been a major supplier to the permanent implant industry. As DuPont has a major fiber presence in Europe it can be assumed that they have also supplied this market. Companies in the Rhône-Poulenc group have apparently also supplied the European implant industry. (The interest or lack of it on the part of these companies in supplying the United States implant market is discussed in a later section.) Therefore, we note that European companies are not likely to be as affected by DuPont's withdrawal as their United States competitors. This is discussed in the Forecasts section.

Potential Suppliers - Most major and smaller United States and foreign producers contacted to date are uninterested in entering this market. From the point of view of exposure to liability many of the largest suppliers of PET yarn are multifaceted international companies often with manufacturing facilities and substantial interests in the United States. A list of United States companies and foreign producers and their willingness to sell into the United States implant market is given below:

<u>Uninterested in entering this market</u>
- Albany International
- BASF (PET business being sold)
- CaMac Corp., Division Cookson America
- Guilford Mills, Inc.,
- Guilford Fibers Division
- Hoechst-Celanese & Hoechst Germany
- Mitsubishi Rayon America
- Rhône-Poulenc
- Toray
- Toyobo America
- Unitika America
- Wellington Synthetic Fibers

<u>Willing to consider or have not ruled it out yet</u>
- Enka (Akzo) [United States Reps I.C.F.]
- Kuraray
- Lewistown Specialty Yarns, Inc.
- Teijin America

<u>Will supply with stringent protective safeguards</u>
- Wellman

Users of DuPont resin, even if presently willing to supply yarn to this industry, may be unable to continue to do so, as DuPont does not want even its resin to be in the chain of supply.

Some foreign producers are possibly willing to sell to third parties such as throwsters ("texturizers") for apparel purposes on a "don't ask, don't tell" basis. Who buys the yarn would then be strictly the business of the third party and its customer. DuPont, on the other hand, is apparently trying to prevent such sales of its yarn.

Wellman, the third largest United States producer of PET yarn (*e.g.*, sold under their Fortrel®, registered trademark) and one of the few companies that also produces its own PET resin, reversed its earlier position of not entering this market and will now sell to the United States implant industry. The conditions under which yarn will be sold and the motivations for supplying it will be discussed in Part II. It should be noted however, that the yarn they are offering is a partially oriented yarn (POY), not the fully oriented polyester yarn used in implants since the 1950's. According to Wellman, when further processed by "others" in the industry (*i.e.*, throwsters) it should come very close to currently used, traditional, fully oriented polyester. However, they will make no warranty to that effect. (We note, it is likely that considerable developmental work will be needed to accomplish this.)

Polytetrafluoroethylene (PTFE)

Background - Major applications of PTFE in implants, so far as raw material bulk consumed, utilize it in fibrous and expanded form, although small amounts are used in other forms (*e.g.*, for coatings). Fabrics made of PTFE fiber have long been used as permanent implants in the human body for purposes similar to those of PET fabrics and patches. They are considered to be inert and benign in these functions. (We note that in the case of the TMJ implant, PTFE in the form of a composite material was exposed to continual mechanical shear, which is known to cause material failure.)

PTFE fabrics are often used as supporting or reinforcing matrices and, as with PET, it has been standard practice to incorporate tiny amounts of them in the form of collars, cuffs or backings as a part of other implants, such as heart valves, to enable suturing to the body.

In the form of tiny felt pads called pledgets, PTFE fiber is extensively used in surgery to buttress friable tissue so that it can be sutured. Many such pledgets are routinely used during replacement of heart valves.

Within the last 20 years, expanded PTFE (ePTFE) in tubular form has become a major material for the construction of medium and smaller diameter vascular grafts. Major permanent implant uses of PTFE are given in Table 4.

TABLE 4 - POLYTETRAFLUOROETHYLENE (PTFE) MAJOR IMPLANT APPLICATIONS

Yarn
- Heart Valve
  - Sewing collar
  - Stent cover
- Surgical fabric, mesh, felt for:
  - heart patch
  - hernia repair
  - pledgets to buttress friable tissue for suturing, *e.g.*:
    - in heart valve replacement
    - arteries
    - liver and others
- Sutures
- Braided Tape

Expanded PTFE
- Vascular graft prostheses
- Surgical patches
- Knee ligaments
- Catheter access ports
- Sutures

Other Uses of PTFE Resin
- Insulator for heart pacing wires
- Suture coating

Quantities of PTFE Consumed By Permanent Implants - The two types of PTFE, yarn and ePTFE, which account for the major volume of PTFE used in implants, are distinct in terms of form, processing, source and availability although they overlap to some extent in implant function. They will therefore be treated as separate materials.

PTFE Yarn - Unlike PET, this is a fairly unique material that is produced by only one other company in the world, Toray, which uses a process similar to DuPont's. In this process, rayon acts as a matrix for fine particles of PTFE, that are sintered on exposure to high temperature to form a continuous filament. At the same time, the heat destroys the matrix leaving a residue on the PTFE fibers. The resultant brown fibers are converted into fabrics that are bleached by thermal or chemical means. The filaments are fairly fine so that relatively soft, supple fabrics can be made

from them. Other processes produce tapes derived from slit films that are likely to give much coarser fabrics with very different properties.

Continuous filament PTFE is used for all of the yarn applications indicated in Table 5 except for felt and pledgets which use staple (*i.e.*, short filament lengths).

All the initial IMS statistical data in this segment for fabrics, felt and pledgets were multiplied by the following factors:

Federal and VA Hospital Correction	1.06
Export Factor	2.0

The OEM factor for pledgets was taken as 1 as these are highly visible in the database as purchases from both the original manufacturers and their OEM clients. The loss factor for pledgets was put at 4 as this process is reportedly highly wasteful. A typical weight of 0.03g was used for pledgets, while the weights of surgical felts were taken as 9 - 20g depending on size, based on fabric density information.

Fabrics using continuous filament PTFE yarn are sold almost exclusively to OEM clients, such as heart valve manufacturers, with almost none of them showing up as hospital purchases. (Only enough to account for about 150 pounds of fiber were found this way.) Based on interviews with knowledgeable industry sources we have therefore estimated industry consumption of continuous filament PTFE fiber at about 1/3 of staple consumption. Estimated poundages for continuous filament were split evenly between 200 and 400 denier yarn. Prices are those currently quoted by DuPont for each item. Estimated consumption of PTFE fiber and implant market size is summarized in Table 5.

TABLE 5 - PTFE YARN IMPLANT CONSUMPTION 1992

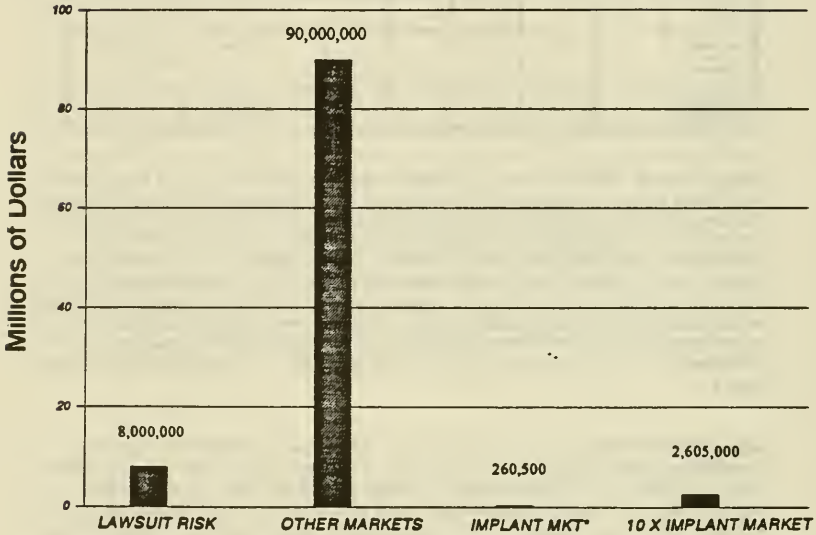
USE	United States UNITS (IMS) 000	WORLD-WIDE UNITS 000	TYPICAL UNIT WEIGHT gms	TOTAL WEIGHT UNITS SOLD kg	TOTAL WEIGHT UNITS SOLD lb	MANU-FACTUR-ING LOSS FACTOR	TOTAL WEIGHT CON-SUMED lb	PTFE $/lb	TOTAL $ PTFE
Pledgets	2,460.5	5,089.06	0.03	153	336	4	1344	24.00	32,256
Surgical Felt	44.1	102.84	9-20g	1243.6	2736	2	5472	24.00	131,328
TOTAL STAPLE							6816	24.00	163,584
CONTINUOUS FILAMENT ESTIMATED TOTAL							2300	30.30 54.00	96,945
TOTAL ALL PTFE FIBERS							9116		260,529

Comparison with Other Markets - The largest markets for PTFE fibers are the United States and Western Europe. According to SRI International, United States consumption of PTFE fibers was about 1 - 1.5 million pounds in 1990 with about as much for Western Europe. Based on an average of current DuPont prices (about $36/lb), the total market is between $36,000,000 - $54,000,000 for the United States and $72,000,000 - $108,000,000 for the United States and Western Europe combined. Sales to the United States implant industry would then account for only 0.24 - .36% of the combined market. Even at 10 times this value the returns would not be commensurate with the possible liability risk if, as with PET, we use DuPont's estimated $8,000,000 annual costs in the TMJ implant cases as a yardstick. This is illustrated in Fig. 2. (The value of the "other" market is taken as $90,000,000 in Fig. 2, the midpoint of the estimated range.)

Supply of PTFE Fiber - DuPont has been virtually the sole source of PTFE fiber used in surgical felts, fabrics and meshes. Toray, the only other company in the world known to make a similar PTFE filament, has followed suit with DuPont and will not supply the United States medical market under current conditions, although it will continue to supply the Japanese market. We note, Toray is not a producer of PTFE resin and must obtain it elsewhere to make this fiber.

Another type of PTFE filament derived from a slit film process is made by Lenzing, an Austrian firm. The product is much coarser than the present filaments and is likely to produce fabrics very different in nature from those that have been widely accepted for years. Supply from this company is, in any case, uncertain. Other companies making PTFE filament are Zeus, which makes only monofilament, and Gore, which makes filament from expanded PTFE. Fabrics that may be derived from either of these are also likely to be substantially different from those currently used. They will have to gain medical acceptance as well as be qualified for the FDA.

Fig. 2: PTFE FIBER MARKETS VS. RISK



* *Fabrics, Felts, and Pledgets*

Expanded PTFE - Expanded PTFE is derived from PTFE fine powder. Processing takes advantage of the ability of this material to fibrillate and produces materials with microporous walls. Major implant uses, so far as raw material bulk consumed, are for vascular grafts and surgical patches.

Estimates of the quantity of PTFE used for these purposes were based on information from the IMS database. All the initial IMS statistical data in this segment were multiplied by the following factors:

Federal and VA Hospital Correction	1.06
Export Factor	2.0

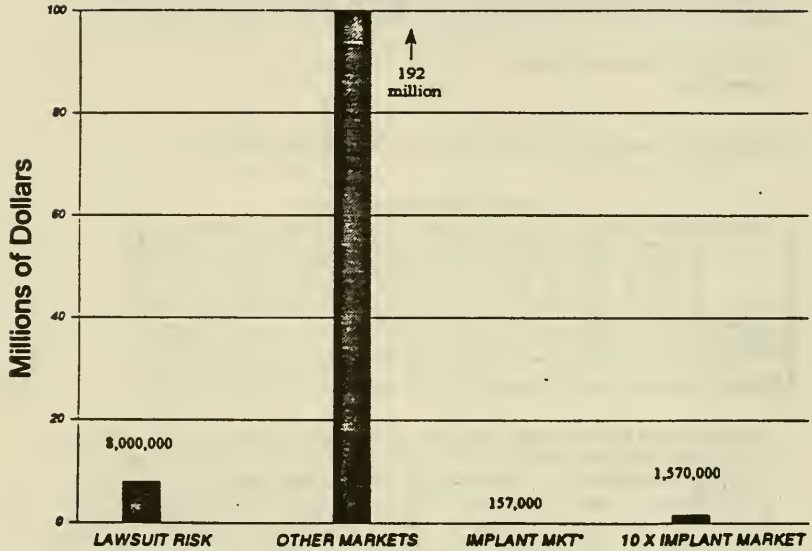
Quantities of PTFE consumed for ePTFE implants are summarized in Table 6.

TABLE 6 - ePTFE IMPLANT CONSUMPTION 1992

USE	United States UNITS (IMS) 000	WORLD-WIDE UNITS 000	TYPICAL UNIT WEIGHT GMS	TOTAL WEIGHT UNITS SOLD kg	TOTAL WEIGHT UNITS SOLD lb	MANU-FACTUR-ING LOSS FACTOR	TOTAL WEIGHT CON-SUMED lb	TOTAL $ PTFE @ $10/lb
Vascular Grafts	152.9	309.9	5.5	1706	5750	5	11,250	112,500
Surgical Patches	54.3	126.6	3- 5.7	671	1481	3	4,444	44,440
TOTAL							15,695	156,940

Comparison with Other Markets: Worldwide consumption of PTFE resins in all forms was approximately 94,000,000 pounds in 1991 with a value of about $705 million. The amount of fine powder (also referred to as coagulated dispersion) PTFE consumed in the United States, Western Europe and Japan in 1991 was about 19.2 million pounds (based on figures published by SRI International). Assuming current prices (about $10/lb), the value of the PTFE fine powder market is about $192 million with permanent implants accounting for about $157,000 or 0.08% of the total. Even at ten times this value, the implant market is not commensurate with the $8,000,000/year yardstick of liability risk. This is seen in Fig. 3, in which the bar for "other" represents only about half of the PTFE fine powder market and on the same scale would have to be about twice as long to represent the full value.

Fig. 3: PTFE F. P.[1] RESIN MARKETS VS. RISK



* *Vascular Grafts and Surgical Patches*

1 *Fine Powder Resin*

Supply of Fine Powder PTFE: DuPont is not necessarily the primary or only supplier of fine powder PTFE to implant manufacturers. In addition to DuPont major suppliers of PTFE resin are:

Ausimont
Daikin
Hoechst
ICI

Ausimont, Daikin and ICI were all reviewing their policies and Hoechst had apparently decided not to supply any of its materials to the United States implant industry, at the time we contacted them. In the event any other supplier decides to halt sales of PTFE to the United States implant industry DuPont will not be available as a fallback. The high capital investment that is apparently needed generally limits PTFE production to major companies. As the same group of companies dominates this business throughout the world, it is possible that supplies of this material to United States medical implant manufacturers could dry up if they follow DuPont's lead. However, medical implant companies that also consume large quantities of PTFE fine powder for non-implant purposes may well be in a position to point out to suppliers that liability risk due to implants is far less significant if measured against total sales. Companies with this sort of leverage might still be able to obtain supplies for implants even if suppliers would prefer to follow DuPont's lead.

"Lifesaving and Life-Enhancing Implant Market" - An estimate of the proportion of PTFE yarn and resin that goes to lifesaving implants as opposed to life-enhancing uses is given in Table 7. Clearly, this can only be roughly estimated. Pledgets, for example, are used to buttress sutures in friable tissue and many are often used in heart valve implant surgery. They may, however, also be used in somewhat less critical procedures. In general, it can be seen that the great bulk of PTFE tracked in this study is likely to go for lifesaving implants.

TABLE 7 - PTFE CONSUMPTION FOR LIFESAVING IMPLANTS

IMPLANT TYPE	USE	TYPE PTFE CONSUMED	% LIFESAVING
Vascular Grafts	Blood vessel replacement, arteriovenous shunts.	ePTFE	100
Patches	Tissue reinforcement.	ePTFE	50
Patches, Meshes, Fabrics, Pledgets	Heart valve sewing rings, stent covers, heart patches, hernia patches, suture buttresses in friable tissue.	Yarn	75

Polyacetal Resin

Background - DuPont's Delrin®, as well as Hoechst Celanese's Celcon®, polyacetal resins have been used for some time to fabricate stents (the supporting rings) used in construction of tissue-based heart valves. Like so many of the materials used by this industry, and even more so than the other materials in this study, the quantity consumed is virtually invisible compared to other uses, yet it serves a critical use, indeed almost all of it in a lifesaving function.

Although tissue heart valve stents are apparently the major use of polyacetal resins in permanent implants, they may be used for spacer rings, or possibly bearing surfaces in other structures.

Quantity Consumed - According to the study, "Soft Tissue Implant Markets," published April 1993 by Frost & Sullivan, the United States prosthetic heart valve market comprised about 65,500 units in 1992. Of these about 22,100 were tissue valves. Industry sources indicate about 5000 tissue valves use polyacetal stents. The majority of these are exported.

The weight of each stent is 1 - 2 grams. Based on information from industry sources, it is reasonable to assume that, depending on the process used, it takes from 5 - 50 grams of material including losses, to make an acceptable stent.

Although DuPont's Delrin® polyacetal resin may be purchased as pellets from DuPont at $1.90 - $1.95/lb in 2200 pound quantities, the price for smaller quantities and other forms may be as high as $6/lb from other sources.

In order to avoid underestimating consumption, we have assumed 50 grams resin are used per heart valve. We have also assumed the highest price, $6/lb. The worldwide total implant consumption would then be about 250 kilograms or 550 pounds with a value of $3300. This is summarized in Table 8.

TABLE 8 - POLYACETAL IMPLANT CONSUMPTION 1992

USE	WORLD-WIDE UNITS	TYPICAL UNIT WEIGHT gms	WEIGHT/UNIT CONSUMED IN MANUFAC-TURED gms	TOTAL WEIGHT CONSUMED @ 50gms/UNIT kgs (lb)	TOTAL $ POLYACETAL @ $6/lb
Tissue Heart Valve Stents	5,000	1 - 2	5 - 50	250 (550)	3300

Comparison with Other Markets - Polyacetals are commodity engineering plastics with major industrial, plumbing, automotive, electrical and consumer article uses, among others. They are produced by about 7 principal manufacturers of polymeric materials. Total consumption of polyacetal for the United States, Western Europe, and Japan in 1991 amounted to 686 million pounds (based on SRI International figures) with a value of about $1,300,000,000 based on current DuPont prices for unfilled resin.

Based on our estimates, which we believe exaggerate consumption, the permanent implant industry represents 0.00025% of this total. The automotive industry which reportedly consumes about 3 pounds resin per car, uses as much as the entire implant industry on about 183 cars. Even a tenfold increase of our dollar estimate to $33,000, is neither significant relative to other markets nor commensurate with our $8,000,000/year yardstick of liability risk.

Supply - Delrin®, and probably Celcon®, polyacetal have apparently been obtained by implant manufacturers in small quantities from third parties rather than directly from the manufacturers. Delrin®, is fairly unique as it is a homopolymer, while most other polyacetals (*e.g.*, Celcon®) are copolymers. Asahi appears to be the only other company in the world, besides DuPont, that makes a homopolymer. According to knowledgeable sources, replacement of Delrin®, with a polyacetal copolymer in an FDA qualified implant would require filing a supplemental premarket approval application (PMA) with the FDA. In a relatively easy case like this, it might still take about a year to get approval to sell the implant with the copolymer.

The following companies manufacturer polyacetal either in the United States or their home countries:

Asahi America
BASF
Hoechst Celanese
Hoechst Germany
Lucky-Goldstar Int'l America,
Korean Engineering Plastics
Mitsubishi Gas and Chemical America

Of these, only BASF, whose "Ultraform" is a copolymer, was willing to at least consider supplying material for permanent medical implants.

Structure of the Material Supply Market

Except for polyester yarn, we note that the number of actual independent manufacturing sources for equivalent replacements of the subject materials worldwide is fewer than 12 companies. In some cases just one or two producing companies exist. These companies are generally well known industrial giants like DuPont.
Although there are about 150 polyester yarn manufacturers worldwide, if the United States pattern holds, we estimate that probably not more than 25% of these are completely independent, in the sense that they manufacture their own PET resin and do not buy it from a major producer. It may also be noted, that PET resin can probably be more easily manufactured on a small scale with relatively small investment compared to PTFE or polyacetal resins.

It appears likely, if the same pattern holds with all of the materials withdrawn by DuPont from the implant industry, that a few major industrial companies will be the only other independent sources for many of them. Our study suggests (see section II) that many of these view supply to the United States implant industry, under present circumstances, in much the same way as DuPont.

II.

MAJOR FACTORS THAT INFLUENCE SUPPLIERS' DECISIONS TO SELL OR NOT TO SELL TO THE PERMANENT IMPLANT MARKET

Background

In discussing the factors that influence suppliers' decisions to sell or not to sell to manufacturers of permanent medical implants, it is worthwhile to consider those that influenced DuPont to allow supply to the permanent implant industry in the first place and to eventually withhold this supply. According to a source familiar with the evolution of DuPont's policy on supply for medical applications, DuPont began, out of a sense of social responsibility. In the 1940's and 1950's, DuPont provided samples of materials it developed to medical researchers who requested them. In its original letters DuPont stated that while it was not interested in entering the field, it did not want to hinder the progress of medical science either.

As a part of this policy, all inquiries for materials to be used in medicine were shunted through a group that dealt with them in a standard manner. A standard letter of response was sent out stating the materials were not made for medical applications and citing references in the medical literature which were illustrative of the need for users to do appropriate testing (*e.g.*, an article on solid state carcinogenesis). DuPont also stipulated that it would not promise continuity of supply or content. The customer had to sign an agreement acknowledging all of the above to obtain material for medical applications. After 1976, references to medical literature were deleted from the letter.

Although this policy has been cited by the courts as evidence in DuPont's favor, it did not prevent them from being sued. The sale of about $0.05 worth of PTFE Teflon® per TMJ implant to the now defunct Vitek resulted in mass litigation, a situation quite different from any DuPont had faced previously in connection with medical implants. DuPont was forced to defend itself in about 1000 cases in 40 states, on a state by state basis, at an estimated minimum out of pocket cost of $8000 per case/year. This ultimately provoked DuPont to withdraw from supplying materials to the permanent medical implant industry.

Contrary to the belief of some decision makers in other companies, DuPont has had to date, only one judgement against it, for about $500,000. They believe they have an excellent chance of overturning this on appeal. Further, DuPont states that more than 258 judgements have been in their favor.

At present DuPont will sell to implant manufacturers when it is involved in the design of the device. An example of this, cited by DuPont was a joint venture with DePuy. In effect, DuPont has to be in the device business with respect to that device to sell material for its manufacture.

In a letter to its customers dated January 15, 1993, to which its policy and a notice of caution were attached, DuPont announced withdrawal of supply to customers that manufacture "medical articles intended for permanent implantation in the human body or in permanent contact with internal body fluids or tissues" and its intention to complete such withdrawal by January 31, 1994. During the intervening period, DuPont permitted customers to obtain supplies so as to allow them time to find

alternate suppliers and/or materials. (The letter of withdrawal, official policy statement and notice of caution for implants are given in Appendix A.)

It would be difficult to overstate the repercussions of the DuPont withdrawal throughout the industries that supply materials to manufacturers of permanent medical implants. In some cases we considered ourselves fortunate that the individuals we spoke to did not simply hang up when the words "supply materials for implants" were spoken. The individuals in responsive companies were all knowledgeable of their companies' policies on this matter, and some participated in forming them. In discussing supplier motivations, we will consider the responses of suppliers of the materials covered in this report as a single group, generally without any categorization by material.

Identification of the Factors

We contacted 36 companies and separate divisions of companies dealing with the materials of interest. Where there was a company-wide policy in place the results from the separate divisions handling each material were lumped together as one company. In some cases the companies contacted were totally unresponsive. Although we had a formal material supplier questionnaire, we soon found that a less formal approach was more productive in the tense atmosphere surrounding this issue. (For example, an informed industry source considered medical applications an "incredibly sensitive area" and stated that they "must be extremely careful.")

Our approach was to explain that HIMA was interested in the supplier's point of view on this issue and, where possible, to engage in a conversation in which we introduced at least the key questions from the questionnaire. In most cases the respondents wanted their identities held confidential. Often they did not wish their responses (beyond whether they were willing to consider supplying this market) to be specifically associated with their companies. Thus, we have not generally associated specific answers with companies.

In our interviews with the 26 companies which were responsive, 11 (42%) were willing to consider supply to the medical implant industry, while the other 15 (58%) would not do so at the present time.

The factors listed in Table 9 emerged as the most important for both groups in making their decisions regarding supply to permanent medical implant manufacturers.

TABLE 9 - FACTORS INFLUENCING SUPPLIERS' DECISIONS TO SELL OR NOT TO SELL

FACTOR	% CONSIDERING THIS FACTOR IN DECISION TO SUPPLY MARKET
Risk of legal liability	85
Small market size	54
FDA (regulatory fears) and medical hassle	27
Humanitarian concerns	15

Analysis of the Factors

Risk of Legal Liability - It is clear that risk of legal liability is the most important factor in determining whether a supplier will sell to this market. One might wonder why, as the above table suggests, less than 100% of those surveyed considered this factor. Our data suggests that certain bulk suppliers of commodities (such as PET yarn and polyacetal resin) simply considered the small market size alone and lost interest at that point. Risk of liability, the extent and consequences of which are really unknown, looms large in the mind of almost anyone considering this market.

We further found that about 23% of all companies were willing to consider some form of indemnification or "held harmless" agreement to persuade them to supply the implant industry. For the most part these companies indicated that such agreements would have to come from financially strong companies or, as suggested in one case, be backed by the government. In addition to such agreements, at least two companies were interested in solid test data to support the appropriateness of the use of their materials. Based on legal advice, two companies were highly skeptical that any indemnification agreement could be completely effective in protecting them from, or compensating them for, the effects of a lawsuit.

Market Size - The second most important factor in deciding whether to supply was market size. Most companies recognized the market was likely to be very small and not worth the risk (several linked these factors in calculations) or indicated the market (or return) would have to be large enough to justify their involvement.

Some reasons why the market size factor did not have an importance equal to liability were:

Exposure to what many evidently consider an inordinately high risk of lawsuit arising from supply to this field was sufficient discouragement without need to even consider market size.

Some major producers which sell to the implant market in other countries, despite its size, simply stated they were following DuPont's lead.

Other producers which do not directly sell to this market in other countries, but unofficially recognize that their materials reach it through third parties, have no interest in the size of the market but are concerned with liability.

Factors other than liability concerns detracted from the importance of market size:

Several companies felt their concern about FDA matters was sufficient to prevent supply, even without considering market size.

Still others were not concerned about the market size (or perhaps accounted it negligible) because they felt it should be supplied for humanitarian reasons.

In one very exceptional case, a niche manufacturer did not consider the tiny market in itself negative. However, the risks of legal liability, and protection from it were considered critical.

FDA, Medical Hassle - An important factor documented in this study, and no doubt familiar to those who have discussed material supply with manufacturers unacquainted with this field, is the belief by manufacturers that they will need FDA approval or have to develop and maintain a master file for the FDA. This taken with either one or both of the above factors and, in at least one case, on its own was a reason not to supply this market. Were the liability issue nonexistent, this impression would probably still keep certain producers out of the market.

Humanitarian - Humanitarian concerns were expressed approximately 15% of the time as a reason for supplying this market. The need to be absolutely protected against the risk of liability while doing so was also expressed by some of these companies.

Other Factors - Other factors affecting producers' decisions to supply or not supply this market were as follows:

Dependence on Others for Raw Materials - Some materials producers, which do not control their own raw material supply, wish to avoid friction with suppliers they depend

on, over the small implant market. For example, small PET yarn producers often obtain PET resin from DuPont. As DuPont apparently does not wish its resin to be converted to yarn that will be used in permanent implants, the yarn producer is reluctant to sell to the implant manufacturer.

Publicity - Being able to advertise about the medical use of materials, especially to save lives, was once considered a benefit of supplying this small market. Although we did not explore this angle extensively, we came away with the impression that at this time companies do not want their materials to be publicly associated with implants. This fits in with the surreptitious atmosphere surrounding this issue: even those willing to supply this industry under any kind of arrangement do not wish this to be publicly known. Clearly, to be publicly associated with implants makes you an easier target for lawsuits. However, some suppliers would just consider it bad publicity at this time.

Very Demanding Marketplace - Variations from standard materials were often wanted for very small volumes of products.

Special Facilities - One producer, which would not supply, in any case, due to market size and liability, stated another reason for this was that they would not "feel comfortable" unless material for this end use were produced in a specially designated area of the plant with special machinery, even though they knew this was not required, and that the regular plant area was clean and orderly.

Conclusions: Forces That Drive This Market

High Liability Risk - The most important factor <u>today</u> from the perspective of the raw material supplier in the decision to supply (or not supply) the implant industry is fear of exposure to costly and possibly catastrophic lawsuits, in an extremely litigious area. This fear is compounded by the inability to predict the extent of and effects of such exposure. Liability could cost a supplier millions in defense or hundreds of millions (even an entire business) in settlements if held as legally responsible as an implant manufacturer. This, coupled with a predictably small return relative to other markets, has created a situation in which most suppliers are not interested in selling to the permanent medical implant market, despite the recognition by many of the societal value in doing so.

We further note that indemnification and "held harmless" agreements may be used to reduce the liability risk.

Some raw material suppliers expressed a willingness to meet the needs of the medical implant industry "as good corporate citizens," if they were freed from liability responsibilities. To some this meant a guarantee that would totally free them from dealing with or paying for any lawsuit arising from use of their materials in implants. Others wanted complete and total indemnification for any expenses arising from such lawsuits.

Initially some smaller producers felt that if the revenue potential were significant versus the risk, they would consider supplying the market (*e.g.*, as with premium prices for PET yarn). However, as they (and their lawyers) considered this issue further, their interest weakened. Indemnification guarantees from financially powerful companies might restore their interest.

For some, however, indemnification agreements are not enough:

Some companies stipulated that they would only consider sales to large reputable companies that could not only indemnify them for any expenses arising from lawsuits, but could also prove that their materials were being appropriately used and had been properly tested for the particular implant. (Note: problems with the Vitek temporo-mandibular joint implant have been attributed to the inappropriate use of PTFE and improper testing.)

Profit - In special cases the possibility for significant revenue to a very small producer, which charges premium prices, and is protected against liability, might also drive supply to this market. With respect to the three subject materials, this factor applies specifically to PET yarn producers; here, there are some small niche manufacturers. However, these manufacturers may not be able to supply this market even if they would like to, as they usually obtain PET resin from larger manufacturers which may object to supplying the makert even indirectly.

Profit and Social Responsibility - Our earlier analysis indicated, that there is little, and in some cases nothing to be gained financially from selling to the permanent medical implant market. Under conditions where the risk of major liability is perceived to be absent or low, producers are more likely to sell their materials to responsible manufacturers of permanent implants. However, even then, producers have reservations as their materials were generally never intended for use in implants.

Despite the above factors, materials are sold to implant manufacturers. Clearly, sales to the medical implant market must be driven by motives other than to profit alone. We conclude that the motivation for sales to manufacturers of permanent medical implants appears to stem from a feeling that medical needs, particularly when they are associated with saving or

improving lives, are in a special category and should be met. This sense of social responsibility has benefitted those whose lives have been saved or vastly improved by the medical implant industry's products.

Currently, fear of being penalized with massive lawsuits for acting in this socially responsible manner is forcing suppliers to avoid the United States permanent implant market. Materials suppliers fear that they too might find themselves in the same situation as DuPont's which has had to spend millions of dollars to contend with lawsuits because it supplied PTFE for a temporo-mandibular joint implant. Materials suppliers are also aware that settlements of cases against implant manufacturers may cost billions of dollars in the United States; suppliers also fear, that should they be held as liable as the implant manufacturer, they will face a similar calamity.

An Example

The case of Wellman, Inc., illustrates some of the factors described above. After DuPont announced it would no longer supply PET for use in permanent medical implants, Wellman received many requests to provide it, which they refused. In January 1994, however, they announced their intention to supply the implant market under certain conditions. As a company spokesperson explained, "someone had to step up", and "this needs to be done." When pressed further on motivation, they said "if you had to go to a hospital, you'd like to feel they had everything there you might need." They stressed that they consider sales to permanent medical implant manufacturers additional business, to be treated in a strictly business-like manner, and that they are not interested in publicly projecting any other motive for making them.

As the third largest polyester producer in the United States, and one of the few that make their own PET resin, Wellman felt they should fill this need, as apparently no other United States company was ready to do so. The absence of problems associated with polyester implants was also cited as a factor in their decision.

Clearly, Wellman felt a sense of social responsibility; however, they intend to make money on these sales and deal with them under strict guidelines including the following:

- They will make no warranties on their product.
- As further processing is required after it leaves their plant, they will not take the position that it will ever be identical to currently used DuPont yarns.
- Appropriateness of use will be the responsibility of the implant manufacturer.

- All responsibility for FDA matters will be in the hands of the implant manufacturer.

Only companies with the financial muscle to back stringent indemnification agreements would be considered for sales by Wellman. They will insist on convincing evidence of the ability of the customer to back indemnification. They apparently recognize that this approach will not help smaller implant makers, but they have no solution for this. Clearly, Wellman is willing to supply only on the grounds that they are substantially protected from the risk of liability.

According to Wellman, it will be inefficient and costly to supply this market as machinery, which can make the quantities required by the implant industry "in the blink of an eye," will have to be diverted from normal production to fill very small orders. Still, they intend to make some money for their trouble. In the event that supplying the implant market costs Wellman money, they will halt sales. They added that they would not be disappointed if they were never called on by any implant manufacturer.

III.

MARKET FORECASTS

Potential for a Biomaterials Shortage for Permanent Implants

The threat of potentially crippling lawsuits, in which suppliers may be held as responsible as the medical implant manufacturer for any problem attributed to the use of the implant, will prevent many from supplying the United States implant market in the first place, and will, no doubt, drive others out of it. To the extent that producers respond to the needs of the industry, in an effort to behave in a socially-responsible way, they will be forced to do it in a highly cautious, wavering manner, laden with legal safeguards. Based on our interviews with suppliers we consider this a fact which colors any forecast of raw material shortages. While our predictions are based on the materials and implants on which this study has focused, we believe they may be applied generally to products used by the implant industry.

Short Term Scenarios (1 - 3 Years)

Size of Reserves - Over the past year DuPont continued to supply the permanent medical implant industry in accord with its stated goal of making sure its "actions do not cause negative economic or safety effects in the health care industry in general" (see Appendix A). The practical effect is that some companies were able to add to their existing reserves of DuPont materials and now some, but probably not all companies have reserves which may last three years. Our sense is that companies using the materials in this study (*e.g.*, PET yarn, PTFE fiber) for the most part will be able to produce normally for at least two and probably three years. However, in some cases, such as with smaller, newer producers, the time frame could be as little as one year.

Potential Shortage - At present, supply to the industry is in turmoil. Although some manufacturers may have potential replacements for materials such as PET yarn, few, if any, have replacement materials that could now be used in FDA qualified implants. A near term shortage would be created if stocks of FDA qualified materials were damaged or destroyed by some calamity, as there are no immediate replacements. For instance, if one of the few companies which dominate supply of polyester vascular grafts and surgical fabrics used as sewing rings for heart valves, lost its reserves, a shortage of these lifesaving implants could result.

Ability to Meet Patient Needs - It appears that, barring calamity within the short term, the industry segment using PET yarn, PTFE yarn and staple (*i.e.*, short fiber lengths) and probably also polyacetal resin will largely be able to supply the needs of patients.

PTFE fine powder resin, used to manufacture ePTFE vascular grafts and patches, presents a somewhat different situation than the other materials in this report as it appears DuPont has not recently been the sole supplier nor the main supplier to manufacturers in this field. Should the other supplier(s), continue to supply the field, there will be no shortage.

However, this situation may change rapidly if the other supplier(s) reconsider(s) their policy. In at least one case, the policy was recently undergoing systematic company-wide review. A crisis could arise if the present supplier(s) withdraws without a grace period. Implant manufacturers might then find themselves with almost nowhere to turn as DuPont will not supply them. As major companies are involved, our sense is that they will follow DuPont's example of allowing a grace period, and therefore the needs of patients will probably be met in the near term.

Long Term Scenarios (3 - 10 Years)

Replacement Testing Time is Key - In the longer term to avoid shortages, FDA approved implants made with replacement materials must be available before reserves of DuPont materials run out. Here, the time needed to qualify candidate replacements for the FDA will be critical. Should the FDA require long term animal and clinical testing before implants made with replacement materials are approved, it is possible that reserves of "FDA qualified" materials may be exhausted before implants made with replacements can be marketed. Delays in finding and qualifying replacement materials, and adjusting existing manufacturing processes for their use could aggravate this situation by postponing the beginning of tests for FDA approval. Should these delays occur with PET yarn for example, a shortage of lifesaving vascular grafts could result.

Change of Suppliers may Delay Implants - Events both in the short and long terms (such as court decisions holding raw material suppliers liable for the failure of implants) could drive both old and new suppliers out of this market, regardless of indemnification agreements. This would force implant makers to find still other suppliers (if there are others) and to repeat the qualification process, adding to the delays described above. (Material equivalence qualification is required each time the supplier changes.) A shortage of lifesaving implants such as PET-based vascular grafts and sewing rings for heart valves could develop from such delays. Further, imports, unless FDA qualified, could not be used to fill this void. The result could be patient mortalities that might have been avoided.

Loss of Reliable Materials - It appears almost certain that some well established, reliable products, which have been the products of choice for surgical procedures, will disappear entirely as stocks of them are depleted. This will be a consequence of the unavailability the materials from which they are made.

For example, at least two items discussed in this study, PTFE yarn (used to make surgical fabrics and meshes) and PTFE staple *(i.e.*, short fiber lengths used to make surgical felts), are virtually unique and cannot be replaced. This is because Toray, the only other

company making an equivalent material, will not supply the United States medical implant market under present conditions. PTFE felt pledgets, long favored to buttress sutures, in cardiovascular surgery and in procedures on friable tissue will disappear. The effect will be to handicap surgeons who routinely use them, often in lifesaving procedures, forcing them to make do with less than what they consider best for the patient.

The same is true for the PTFE fabrics and meshes used for heart patches, sewing rings (used to suture heart valves to tissue), and stent covers for heart valves. Although PET fabric might often serve the same function, many surgeons have long used PTFE, prefer it, and consider it best for the patient. In any case, PET yarn, for this purpose, may be unavailable.

Replacements, based on expanded PTFE fiber may appear, but these products will have different characteristics and will, no doubt, need considerable testing before they can be used in critical surgery, and before the FDA permits their use in medical implants.

Impact on the Permanent Medical Implant Industry

Immediate and Short Term Impact (1 - 3 Years)

The present supply situation is likely to impact the operation of the permanent medical implant industry for at least the next 1 - 3 years. Some of the immediate effects, as reported by knowledgeable sources, are:

1) The continuation of searches for equivalent replacements of well-established materials, long used in major product lines, as well as for reliable suppliers. (According to one source, replacements must be found for 27 materials.) This will require the continued diversion of skilled personnel and money away from product improvement and new product development towards:

   a) task forces whose aim is to find replacements for existing materials DuPont has withdrawn;

   b) continued testing and evaluation of new candidate materials;

   c) FDA qualification of technically acceptable candidates.

2) The prospect that the above activities will continue for the foreseeable future due to the instability of the supply situation.

3) The inability of United States implant companies to obtain new materials of any kind, from polymers to integrated circuits, from other companies due to fear of high liability costs.

4) The imposition, by suppliers, of indemnification agreements on implant manufacturers, as a condition of sale, with sales only to those financially able to back them.

In short, an enormous amount of effort and money is now being spent, and will continue to be spent, by the industry to get back to where it was about one year ago.

Although not usually a significant factor relative to the price of the final product, it should be noted that greater premiums will likely be paid for raw materials.

Long Term Impact (3 - 10 Years)

Along with these short term effects, many of which appear likely to continue into the long term, the following long term scenarios seem likely based on an analysis of discussions with industry sources:

Emergence of New Suppliers/Supply Instability - If the present situation continues, all companies will face an era of supply instability and discomfort with supply patterns. New suppliers may emerge for some commodity materials such as PET yarn, for which there are about 150 producers worldwide. However, there may be no new suppliers for other materials such as polyacetal, for which there are probably fewer than a dozen independent producers.

Under any circumstances, including indemnification agreements, new and old suppliers with United States interests will want to be in a position to back out if they consider the risk of liability, and the consequences thereof, too uncomfortable to live with. The results will be the perpetual seeking of replacement suppliers for essential materials and a continuing need to requalify new supplier materials for the FDA. Where old materials are no longer available, substitutes to fill their functions will have to be found and qualified.

With continuation of the present circumstances, offshore raw material suppliers, with insignificant United States assets and few United States employees, will be the best source of raw materials as judgements decreed against them by United States courts may be totally unenforceable in practice, and to sue them in their home countries may be equally impractical. Hence, raw material supply, where possible, may move offshore.

Effect On Industry Structure - Both large and small manufacturers contacted, believed that small medical implant companies would be hardest hit by supply problems. They noted that small manufacturers are not in a position to guarantee adequate indemnification to the supplier or to devote resources to finding and requalifying materials from new suppliers. By offering new or improved products, small companies can enter the market, and may be able to compete effectively. Such companies are frequently highly innovative. It should be noted that large health care corporations have often benefitted by acquiring small, innovative companies. Even today, the great majority of device and implant manufacturers are small and thus form the backbone of the industry.

The inability of small companies to obtain the materials they need to operate will put them in a weakened position versus their competitors, leading to the demise of some and the acquisition of others by larger companies with the financial muscle to deliver on indemnification agreements. New small companies will be discouraged from starting up in this field. To the extent that they do, they may be forced into joint ventures or partnerships with other companies, foreign and domestic, which can supply the raw materials or the backing for indemnification. Given all these factors, the disappearance of independent small implant companies can be foreseen in the longer term.

Conversely, major corporations which supply materials to this industry might, to some extent, benefit from this trend. By selling the finished implant, rather than only the raw materials used in making it, the ratio of liability risk to return becomes much more favorable. For example, apparently even DuPont will continue to supply materials to implant businesses which it owns or in which it has an interest, rather than leave this field entirely. Other large materials suppliers may find acquisition of implant companies that use their materials a more attractive solution than staying out of this market completely.

Effect On Global Competitiveness - While almost the entire United States medical implant industry has had to divert considerable resources simply to maintain status quo production of existing, often long accepted products, its foreign competitors are not faced with a disadvantage of the same scale. Foreign medical implant manufacturers will have an easier time obtaining replacement materials from foreign suppliers as sales to them are apparently not considered as risky as to their United States counterparts. European implant manufacturers, for example, can still obtain PET yarn, albeit sometimes indirectly, from European companies. In the long term, if the United States industry must continuously find new suppliers of old raw materials for existing products, qualify these materials for the FDA, and encounters difficulties in obtaining new materials for improved products, it will lose ground to its foreign competitors. This, along with the loss of innovative small manufacturers, will inevitably lead to the loss of international leadership by the United States in the medical implant industry.

In another scenario, implant manufacturers may be forced to market advanced devices based on new materials only available outside the United States to reduce the risk of mass lawsuits involving the materials supplier. As a result, the American public may find itself deprived of the best lifesaving devices (*e.g.*, heart valves) the United States implant industry has to offer!

Emergence of Alternate Materials to Dacron®, Teflon® and Delrin® For Permanent Implants - The very same issues of liability risk will affect the long term any emergence of any materials based on new polymers to replace PET, PTFE, polyacetal. The major chemical companies which are uncertain sources of old materials for today's market are also the most likely sources of new materials. One of the major effects of the current supply situation, will be a reduction in the flow of new materials to the United States implant industry. As stated earlier, this situation might change if a producer with a material especially suitable for an implant shares in its development, as DuPont suggested it might do (see Appendix A).

It is possible that companies might supply new materials under royalty arrangements where they consider the prospect of return high versus the liability risk, especially when reassured by test data that their material is being appropriately used. To attract a supply of new materials for use in permanent implants, royalty arrangements may become more common. If the present circumstances continue, or worsen, such arrangements will be too risky, and probably will have little effect on the trend away from supplying the permanent medical implant market.

IV.

INFORMATION RESOURCES

Information in this report was compiled from sources familiar with and connected to the permanent implant industry, including 14 industry companies and materials manufacturing companies as:

Acheson Colloids
Port Huron, Michigan

Albany International Corp.
Albany International Monofilament Plant Division
Homer, New York

Asahi America, Inc.
New York, New York

Ausimont, USA, Inc.
Morristown, New Jersey

BASF Corporation
Parsippany, New Jersey

BASF Corporation - Fibers Division
Enka North Carolina

CaMac Corporation
Subsidiary of Cookson America Inc., Plastics Sector
Bristol, Virginia

Daikin America, Inc.
Orangeburg, New York

E.I. du Pont de Nemours and Co.
Wilimington, Delaware

Enka (Akzo) AG (Deutschland)
Wuppertal, Germany

Guilford Mills, Inc.
Guilford Fibers Division
Fuquay-Varina, North Carolina

Hoechst AG
Bobingen, Germany

Hoechst Celanese, Inc.
Summit, New Jersey

I.C.F.
(United States Representative, Enka)
New York, New York

ICI Americas, Inc.
Wilmington, Delaware

Johnson Filament, Inc.
Williston, Vermont

Kuraray International Corp.
New York, New York

Lenzing Aktiengesellschaft
Bobingen, Germany

Lewistown Specialty Yarns, Inc.
Lewistown, Pennsylvania

Lucky-Goldstar International America
Korean Engineering Plastics
Englewood Cliffs, New Jersey

Mitsubishi Gas and Chemical America, Inc.
New York, New York

Mitsubishi Rayon America, Inc.
New York, New York

Polymers, Inc.
Middlebury, Vermont

Shamrock Technologies
Newark, New Jersey

Teijin America Inc.
New York, New York

Toyobo America, Inc.
New York, New York

Unitika America Corp.
New York, New York

Wellington Synthetic Fibers, Inc.
Leesville, South Carolina

Wellman, Inc. - Fibres Division
Fayetteville, North Carolina

Whitford Corporation
West Chester, Pennsylvania

Zeus Industrial Products, Inc.
Raritan, New Jersey

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Appendix A

January 15, 1993

Dear (Customer's Name):

This communication affects only those customers who use Du Pont materials in implantable medical devices.

Recently Du Pont has determined that unpredictable and excessive costs of doing business with manufacturers of implantable medical devices no longer justifies unrestricted sale of standard raw materials to such manufacturers at customary prices. Our new Policy and Caution Statement regarding these sales are attached. Under Du Pont's new Policy there is a very strong presumption against sales to customers making permanent implants.

Therefore, as of January 15, 1993, Du Pont will begin to phase out sale of materials to customers using our materials in medical articles intended for permanent implantation in the human body or in permanent contact with internal body fluids or tissues. We intend to complete this phase out as soon as possible, but no later than January 31, 1994. To allow our customers time to locate alternate suppliers of materials, or alternate materials, during this phase out period we will honor our existing customer/supplier relationships.

Also, effective immediately Du Pont will restrict sales of materials to companies who use those materials in medical articles intended for brief or temporary implantation in the human body or in contact with internal body fluids or tissues. Du Pont will not supply the material to customers making temporary implants, unless the material comes directly from Du Pont under a contract which expressly acknowledges the contemplated use and contains specific business risk management requirements.

Permission to refer to material Master Files will be withdrawn, and given only to direct customers who are purchasing material from Du Pont under contract. We intend to complete transition to this type of supplier/customer relationship as soon as possible, but no later than January 31, 1994.

Unless expressly agreed by contract, do not make reference to the Du Pont name or any Du Pont trademark in association with any implantable medical device. Do not use a Du Pont trademark as the descriptive name of an implantable medical device.

A copy of Du Pont's Policy and Caution are attached. We sincerely regret any inconvenience this may cause you. If you have any questions, please contact me at (xxx-xxx-xxxx).

Sincerely,

DuPont
1007 Market Street
Wilmington, DE 19898

DUPONT

DUPONT POLICY REGARDING MEDICAL APPLICATIONS OF DUPONT MATERIALS

This policy does not affect those customers who use DuPont materials in non-implantable medical articles.

DuPont has determined that unpredictable and excessive costs of doing business with manufacturers of implantable medical devices no longer justifies unrestricted sale of standard raw materials to such manufacturers at customary prices.

GUIDING PRINCIPLES

There are four principles which guide DuPont's approach to this area.

1. NEUTRAL EFFECT ON HEALTH INDUSTRIES

Our first goal is to make sure that our actions do not cause negative economic or safety effects in the health care industry in general.

2. PROTECTION OF DUPONT BUSINESSES

Our second goal is to identify areas where DuPont businesses are involved with the health care industry, and structure those business operations to assess business risks and reduce them to an acceptable level.

3. FDA AND REGULATORY COMPLIANCE

Our third goal is to maintain a positive relationship with the FDA and any other regulatory agencies.

4. DEVELOPMENT OF HEALTH INDUSTRY BUSINESSES

Our fourth goal is to identify and encourage DuPont businesses to develop "managed risk" relationships with members of the health care industry which will result in delivery of high value medical products.

In order to manage business risk in this area DuPont will not supply DuPont materials in the ordinary course of business to firms using such materials for medical applications involving permanent implantation in the human body. There are exceptions to this rule where DuPont is involved in the design of the medical article itself or where business risk management strategies are adequate to justify a supplier/customer relationship.

Continued on reverse side

DUPONT POLICY REGARDING MEDICAL APPLICATIONS
OF DUPONT MATERIALS continued

Frequently DuPont materials end up in medical applications through indirect sales. Supplier/customer relationships with distributors or resellers will be tailored to discourage the use of DuPont materials consistent with this Policy.

Unless expressly agreed by contract, DuPont product names, trademarks and the name of the Company may not be used in conjunction with either permanent or temporary implantable devices, and customers should not represent to others that DuPont permits, recommends, or endorses the use of our materials in implantable medical devices.

CATEGORY A: MEDICAL APPLICATIONS INVOLVING PERMANENT IMPLANTATION IN THE HUMAN BODY OR PERMANENT CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES

Unless DuPont is involved in the design of the medical article itself, there is a strong presumption that business risk management strategies will not be adequate to justify a supplier/customer relationship in such businesses.

CATEGORY B: MEDICAL APPLICATIONS INVOLVING BRIEF OR TEMPORARY IMPLANTATION IN THE HUMAN BODY OR CONTACT WITH INTERNAL HUMAN BODY FLUIDS OR TISSUES

There is a presumption that business risk management strategies can be implemented which are adequate to justify a supplier/customer relationship in such business. Acceptable business terms necessary for forming such customer relations will be required. DuPont will not supply materials to customers with these applications, unless the material is provided directly from DuPont to the customer under a contract which expressly acknowledges the contemplated use. Permission to refer to material Master Files will be restricted, and given only to direct customers who are purchasing material under contract.

CATGORY C: ALL OTHER MEDICAL APPLICATIONS

DuPont will use normal good business judgment in forming supplier/customer relationships. No special risk management strategies are required.

DuPont
1007 Market Street
Wilmington, DE 19898

DUPONT

CAUTION

DO NOT USE DUPONT MATERIALS IN MEDICAL APPLICATIONS INVOLVING PERMANENT IMPLANTATION IN THE HUMAN BODY OR PERMANENT CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.

DO NOT USE DUPONT MATERIALS IN MEDICAL APPLICATIONS INVOLVING BRIEF OR TEMPORARY IMPLANTATION IN THE HUMAN BODY OR CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES UNLESS THE MATERIAL HAS BEEN PROVIDED DIRECTLY FROM DUPONT UNDER A CONTRACT WHICH EXPRESSLY ACKNOWLEDGES THE CONTEMPLATED USE.

DUPONT MAKES NO REPRESENTATION, PROMISE, EXPRESS WARRANTY OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OF THESE MATERIALS FOR USE IN IMPLANTATION IN THE HUMAN BODY OR IN CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.

THE CONTENT OF DUPONT MATERIAL IS NOT CERTIFIED FOR IMPLANTS
DuPont materials are not designed or manufactured for use in implantation in the human body or in contact with internal body fluids or tissues. DuPont has not performed clinical testing of these materials for implantation. DuPont will not provide to customers making implantable devices any notice concerning its materials, as specified under 21 C.F.R. section 820.81, or any other information necessary for medical device use of the materials under any other statute or FDA regulation. DuPont has neither sought, nor received, approval from the FDA for the use of these materials in implantation in the human body or in contact with internal body fluids or tissues.

DO NOT MAKE REFERENCE TO THE DUPONT NAME OR ANY DUPONT TRADEMARK IN ASSOCIATION WITH AN IMPLANTABLE MEDICAL DEVICE
Do not use a DuPont trademark as the descriptive name of an implantable medical device (e.g. do not call it the "Dacron" prosthesis").

ALL IMPLANTABLE MEDICAL DEVICES CARRY A RISK OF FAILURE AND ADVERSE CONSEQUENCES
Regarding implantation of materials, you should rely upon the medical judgment of the physician, the medical device seller and the FDA. Do not rely upon DuPont. Examples of both harmful consequences and life-saving benefits from the implantation of various materials can be found in published medical articles. Without performing clinical medical studies of an implantable medical device, DuPont cannot weigh the benefits against the risks of that device and cannot offer a medical judgment on the safety or efficacy of the use of our material in that device.

Appendix B

DATABASE FOR THIS REPORT

SCOPE - Information in the Hospital Supply Index represents the purchases of medical/surgical supplies by non-federal, non-psychiatric hospitals in the continental United States. Products included are generally for patient support rather than therapy and do not include more expensive equipment items which are capitalized or leased. Purchases made by federal hospitals, psychiatric hospitals, physicians' offices, nursing homes, ambulatory surgicenters, and exports are not included. The current IMS hospital universe is detailed on the following pages.

SAMPLE - IMS maintains a sample of approximately 350 hospitals from which purchase information is gathered monthly. Panel hospitals include for-profit and not-for-profit hospitals, both private and city-county-state facilities, and a representation of teaching hospitals as well as members of large purchasing groups. The sample is balanced by type of hospital, bed size, and region and is also weighted to represent the variability of purchasing among hospitals.

METHODOLOGY - The purchase information obtained from the hospital panel is projected to national levels (continental United States) using a universe over sample projection system. The dollars and units from each hospital invoice are projected dollars by projected units for the current quarter.

All data shown represent the actual purchase by the hospital as it appears on the invoices, whether purchased from a manufacturer or a dealer. Although prompt payment cash discounts and bottom line invoice discounts may exist, they are not reflected in the IMS dollar purchase amounts. Rebates are not included; however, invoiced free goods are reflected in the dollar purchase amounts.

UNIVERSE UPDATE - Each year the total universe for the Hospital Supply Market Report is revised based on the most currently published American Hospital Association Annual Survey of Hospitals.

The national total of hospitals, the IMS sample design, the actual number of reporting in the current quarter follows:

Universe, HSI Sample Design, and Actual Reporting Sample Hospitals
By Hospital Ownership Type and Bed Size.

Ownership Type	Bed Size	National Total	HSI Sample Design	Actual Reporting Sample 93Q3
Private	500 + Beds	225	68	60
	300 - 499 Beds	551	83	75
	200 - 299 Beds	651	61	58
	100 - 199 Beds	1,077	52	52
	1 - 99 Beds	1,431	24	27
Private		3,935	288	272
City-County-State	500 + Beds	56	19	10
	300 - 499 Beds	68	11	13
	200 - 299 Beds	87	7	8
	100 - 199 Beds	234	12	13
	1 - 99 Beds	995	13	10
City-County-State		1,440	62	54
		5,375	350	326

Universe, HSI Sample Design, and Actual Reporting Sample Hospitals
By Census Region.

Census Region	National Total	HSI Sample Design	Actual Reporting Sample 93Q3
New England	234	17	16
Mid Atlantic	568	71	64
South Atlantic	814	61	54
East North Central	823	60	61
East South Central	474	26	27
West North Central	731	32	25
West South Central	769	33	28
Mountain	356	14	12
Pacific	606	36	39
	5,375	350	326

C-4

C-4

Universe and Actual Reporting Sample Hospitals
By Hospital Ownership Type and Surgical Operations.

Ownership Type	Surgical Operations	National Total	Actual Reporting Sample 93Q3	Sampling Rate (%)
Private	10,000 + Surg Ops	547	92	16.8
	7,500 - 9,999 Surg Ops	358	52	14.5
	5,000 - 7,499 Surg Ops	545	43	7.9
	2,500 - 4,999 Surg Ops	836	53	6.3
	1 - 2,499 Surg Ops	1,649	32	1.9
Private		3,935	272	
City-County-State	10,000 + Surg Ops	66	14	21.2
	7,500 - 9,999 Surg Ops	42	9	21.4
	5,000 - 7,499 Surg Ops	84	10	11.9
	2,500 - 4,999 Surg Ops	147	9	6.1
	1 - 2,499 Surg Ops	1,101	12	1.1
City-County-State		1,440	54	
		5,375	326	

C-5 C-5

Universe and Actual Reporting Sample Hospitals
By Hospital Ownership Type and Admissions.

Ownership Type	Admissions	National Total	Actual Reporting Sample 93Q3	Sampling Rate (%)
Private	20,000 + Adms	203	53	26.1
	15,000 - 19,999 Adms	223	37	16.6
	10,000 - 14,999 Adms	463	64	13.8
	5,000 - 9,999 Adms	902	63	7.0
	1 - 4,999 Adms	2,144	55	2.6
Private		3,935	272	-
City-County-State	20,000 + Adms	42	9	21.4
	15,000 - 19,999 Adms	41	7	17.1
	10,000 - 14,999 Adms	66	11	16.7
	5,000 - 9,999 Adms	109	11	10.1
	1 - 4,999 Adms	1,182	16	1.4
City-County-State		1,440	54	
		5,375	326	

C-6

C-6

Universe and Actual Reporting Sample Hospitals
By Hospital Ownership Type and Open-Heart Procedures.

Ownership Type	Open-Heart Procedures	National Total	Actual Reporting Sample 93Q3	Sampling Rate (%)
Private	1000 + O-H Procs	56	19	33.9
	500 - 999 O-H Procs	121	28	23.1
	250 - 499 O-H Procs	227	31	13.7
	1 - 249 O-H Procs	393	39	9.9
	Non Open-Heart	3,138	155	4.9
Private		3,935	272	
City-County-State	1000 + O-H Procs	4	3	75.0
	500 - 999 O-H Procs	11	2	18.2
	250 - 499 O-H Procs	27	4	14.8
	1 - 249 O-H Procs	69	9	13.0
	Non Open-Heart	1,329	36	2.7
City-County-State		1,440	54	
		5,375	326	

C-7 C-7

Universe and Actual Reporting Sample Hospitals
By Hospital Ownership Type and Bed Size and Pacemaker Status.

Ownership Type	Bed Size Pacemaker Status	National Total	Actual Reporting Sample 9303	Sampling Rate (%)
Private	500 + Beds, Pacer	219	59	26.9
	300 - 499 Beds, Pacer	532	75	14.1
	200 - 299 Beds, Pacer	614	58	9.4
	100 - 199 Beds, Pacer	771	44	5.7
	1 - 99 Beds, Pacer	312	11	3.5
	Non-Pacemaker	1,487	25	1.7
Private		3,935	272	
City-County-State	500 + Beds, Pacer	52	10	19.2
	300 - 499 Beds, Pacer	60	11	18.3
	200 - 299 Beds, Pacer	71	8	11.3
	100 - 199 Beds, Pacer	118	10	8.5
	1 - 99 Beds, Pacer	97	7	7.2
	Non-Pacemaker	1,042	8	0.8
City-County-State		1,440	54	
		5,375	326	

C-8 C-8

Universe and Actual Reporting Sample Hospitals
By Hospital Ownership Type and Bed Size and PTCA Status.

Ownership Type	Bed Size PTCA Status	National Total	Actual Reporting Sample 93Q3	Sampling Rate (%)
Private	500 + Bed, PTCA	183	49	26.8
	300 - 499 Bed, PTCA	303	44	14.5
	200 - 299 Bed, PTCA	177	18	10.2
	100 - 199 Bed, PTCA	69	4	5.8
	1 - 99 Bed, PTCA	4	0	0.0
	Non-PTCA	3,199	157	4.9
Private		3,935	272	
City-County-State	500 + Bed, PTCA	43	8	18.6
	300 - 499 Bed, PTCA	42	6	14.3
	200 - 299 Bed, PTCA	17	3	17.6
	100 - 199 Bed, PTCA	7	0	0.0
	Non-PTCA	1,331	37	2.8
City-County-State		1,440	54	
		5,375	326	

C-9 C-9

1993 U.S. Hospital Universe By Hospital Type, Bed Size, and Census Region
Source: 1992 American Hospital Association Annual Survey of Hospitals

	Hospitals	Staffed Beds	Admissions	Census Beds
All Hospitals	5,375	923,692	31,001,793	610,105
Private	3,933	754,896	25,916,115	501,456
500 + Beds	225	154,575	5,499,522	117,985
New England	9	6,460	264,205	5,300
Mid Atlantic	60	42,046	1,422,753	35,918
South Atlantic	33	22,741	804,315	16,668
East North Central	49	32,371	1,177,647	24,193
East South Central	16	10,935	388,075	7,754
West North Central	19	14,138	471,170	10,051
West South Central	21	14,104	496,324	9,585
Mountain	5	3,299	132,610	2,346
Pacific	13	8,481	342,423	6,170
300 - 499 Beds	549	207,600	7,665,561	145,183
New England	32	11,896	466,812	9,301
Mid Atlantic	108	41,703	1,554,917	33,580
South Atlantic	100	37,908	1,389,781	26,217
East North Central	106	40,481	1,454,875	26,899
East South Central	29	10,917	389,333	7,337
West North Central	43	16,177	554,270	10,467
West South Central	43	16,399	588,738	10,327
Mountain	20	7,453	285,151	4,772
Pacific	68	24,666	981,684	16,283
200 - 299 Beds	651	158,201	5,551,702	105,883
New England	43	10,491	376,939	7,462
Mid Atlantic	143	34,005	1,164,788	26,268
South Atlantic	113	27,605	949,092	17,875
East North Central	119	29,653	1,026,791	19,062
East South Central	33	7,911	274,460	4,843
West North Central	43	10,638	313,966	6,791
West South Central	55	13,534	441,077	8,078
Mountain	36	8,767	342,029	5,494
Pacific	66	15,597	662,560	10,010

C-10 C-10

1993 U.S. Hospital Universe By Hospital Type, Bed Size, and Census Region
Source: 1992 American Hospital Association Annual Survey of Hospitals

	Hospitals	Staffed Beds	Admissions	Census Beds
100 - 199 Beds	1,077	152,888	4,925,922	90,436
New England	58	8,487	303,361	5,670
Mid Atlantic	129	18,963	615,425	13,510
South Atlantic	186	26,215	856,177	15,932
East North Central	177	25,744	796,515	14,955
East South Central	87	11,785	356,992	6,430
West North Central	85	12,077	289,824	7,341
West South Central	145	20,052	628,616	10,338
Mountain	53	6,998	249,296	3,883
Pacific	157	22,567	829,716	12,377
1 - 99 Beds	1,431	81,632	2,273,408	41,969
New England	77	4,687	144,267	2,919
Mid Atlantic	93	5,997	171,784	3,898
South Atlantic	183	10,394	305,163	5,558
East North Central	218	13,217	360,211	6,499
East South Central	150	8,694	243,398	4,283
West North Central	241	12,486	260,060	6,423
West South Central	195	11,012	296,097	4,991
Mountain	123	6,095	183,730	3,220
Pacific	151	9,050	308,698	4,178

C-11 C-11

1993 U.S. Hospital Universe By Hospital Type, Bed Size, and Census Region
Source: 1992 American Hospital Association Annual Survey of Hospitals

	Hospitals	Staffed Beds	Admissions	Census Beds
All Hospitals	5,375	923,692	31,001,793	610,105
City-County-State	1,442	168,796	5,085,678	108,649
500 + Beds	56	39,436	1,352,879	31,128
Mid Atlantic	13	9,113	241,166	8,001
South Atlantic	19	13,456	494,377	10,339
East North Central	6	4,435	147,657	3,359
East South Central	6	3,620	141,973	2,643
West North Central	2	1,434	50,698	1,074
West South Central	7	4,809	188,973	3,659
Mountain	1	501	18,307	356
Pacific	2	2,068	69,728	1,697
300 - 499 Beds	70	26,936	989,822	19,545
New England	2	710	27,848	575
Mid Atlantic	7	2,842	80,853	2,391
South Atlantic	12	4,528	167,123	3,165
East North Central	6	2,383	74,896	1,712
East South Central	10	3,773	138,244	2,699
West North Central	6	2,328	70,113	1,523
West South Central	7	2,549	98,167	1,695
Mountain	5	1,847	79,717	1,315
Pacific	15	5,976	252,861	4,470
200 - 299 Beds	87	21,555	758,676	14,125
New England	2	519	15,837	342
Mid Atlantic	2	409	7,928	329
South Atlantic	14	3,631	135,310	2,622
East North Central	10	2,603	78,004	1,659
East South Central	12	2,893	90,856	1,524
West North Central	7	1,585	41,157	950
West South Central	16	3,958	146,335	2,508
Mountain	4	959	40,997	671
Pacific	20	4,998	202,252	3,520

C-12 C-12

1993 U.S. Hospital Universe By Hospital Type, Bed Size, and Census Region
Source: 1992 American Hospital Association Annual Survey of Hospitals

	Hospitals	Staffed Beds	Admissions	Census Beds
100 - 199 Beds	234	32,615	876,566	21,091
New England	3	496	14,816	334
Mid Atlantic	4	654	13,183	509
South Atlantic	51	7,293	212,528	4,990
East North Central	35	4,574	102,231	2,553
East South Central	39	5,622	136,352	3,679
West North Central	32	4,102	66,169	2,847
West South Central	38	5,383	169,699	3,225
Mountain	15	2,008	50,357	1,132
Pacific	17	2,483	111,231	1,822
1 - 99 Beds	995	48,254	1,107,735	22,760
New England	8	407	12,788	271
Mid Atlantic	9	441	9,711	271
South Atlantic	103	5,848	153,422	2,875
East North Central	97	5,905	158,140	2,645
East South Central	92	5,680	143,854	2,803
West North Central	253	11,243	195,204	5,473
West South Central	242	10,101	251,937	3,880
Mountain	94	4,088	70,400	2,261
Pacific	97	4,541	112,279	2,281

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1993 U.S. Hospital Universe By Hospital Type, Census Region, and Bed Size
Source: 1992 American Hospital Association Annual Survey of Hospitals

	Hospitals	Staffed Beds	Admissions	Census Beds
All Hospitals	5,375	923,692	31,001,793	610,105
Private	3,933	754,896	25,916,115	501,456
New England	219	42,021	1,555,584	30,652
500 + Beds	9	6,460	264,205	5,300
300 - 499 Beds	32	11,896	466,812	9,301
200 - 299 Beds	43	10,491	376,939	7,462
100 - 199 Beds	58	8,487	303,361	5,670
1 - 99 Beds	77	4,687	144,267	2,919
Mid Atlantic	533	142,714	4,929,667	113,174
500 + Beds	60	42,046	1,422,753	35,918
300 - 499 Beds	108	41,703	1,554,917	33,580
200 - 299 Beds	143	34,005	1,164,788	26,268
100 - 199 Beds	129	18,963	615,425	13,510
1 - 99 Beds	93	5,997	171,784	3,898
South Atlantic	615	124,863	4,304,528	82,250
500 + Beds	33	22,741	804,315	16,668
300 - 499 Beds	100	37,908	1,389,781	26,217
200 - 299 Beds	113	27,605	949,092	17,875
100 - 199 Beds	186	26,215	856,177	15,932
1 - 99 Beds	183	10,394	305,163	5,558
East North Central	669	141,466	4,816,039	91,608
500 + Beds	49	32,371	1,177,647	24,193
300 - 499 Beds	106	40,481	1,454,875	26,899
200 - 299 Beds	119	29,653	1,026,791	19,062
100 - 199 Beds	177	25,744	796,515	14,955
1 - 99 Beds	218	13,217	360,211	6,499

1993 U.S. Hospital Universe By Hospital Type, Census Region, and Bed Size
Source: 1992 American Hospital Association Annual Survey of Hospitals

	Hospitals	Staffed Beds	Admissions	Census Beds
East South Central	315	50,242	1,652,258	30,647
500 + Beds	16	10,935	388,075	7,754
300 - 499 Beds	29	10,917	389,333	7,337
200 - 299 Beds	33	7,911	274,460	4,843
100 - 199 Beds	87	11,785	356,992	6,430
1 - 99 Beds	150	8,694	243,398	4,283
West North Central	431	65,516	1,889,290	41,073
500 + Beds	19	14,138	471,170	10,051
300 - 499 Beds	43	16,177	554,270	10,467
200 - 299 Beds	43	10,638	313,966	6,791
100 - 199 Beds	85	12,077	289,824	7,341
1 - 99 Beds	241	12,486	260,060	6,423
West South Central	459	75,101	2,450,852	43,319
500 + Beds	21	14,104	496,324	9,585
300 - 499 Beds	43	16,399	588,738	10,327
200 - 299 Beds	55	13,534	441,077	8,078
100 - 199 Beds	145	20,052	628,616	10,338
1 - 99 Beds	195	11,012	296,097	4,991
Mountain	237	32,612	1,192,816	19,715
500 + Beds	5	3,299	132,610	2,346
300 - 499 Beds	20	7,453	285,151	4,772
200 - 299 Beds	36	8,767	342,029	5,494
100 - 199 Beds	53	6,998	249,296	3,883
1 - 99 Beds	123	6,095	183,730	3,220
Pacific	455	80,361	3,125,081	49,018
500 + Beds	13	8,481	342,423	6,170
300 - 499 Beds	68	24,666	981,684	16,283
200 - 299 Beds	66	15,597	662,560	10,010
100 - 199 Beds	157	22,567	829,716	12,377
1 - 99 Beds	151	9,050	308,698	4,178

C-15 C-15

1993 U.S. Hospital Universe By Hospital Type, Census Region, and Bed Size
Source: 1992 American Hospital Association Annual Survey of Hospitals

	Hospitals	Staffed Beds	Admissions	Census Beds
11 Hospitals	5,375	923,692	31,001,793	610,105
City-County-State	1,442	168,796	5,085,678	108,649
New England	15	2,132	71,289	1,522
300 - 499 Beds	2	710	27,848	575
200 - 299 Beds	2	519	15,837	342
100 - 199 Beds	3	496	14,816	334
1 - 99 Beds	8	407	12,788	271
Mid Atlantic	35	13,459	352,841	11,501
500 + Beds	13	9,113	241,166	8,001
300 - 499 Beds	7	2,842	80,853	2,391
200 - 299 Beds	2	409	7,928	329
100 - 199 Beds	4	654	13,183	509
1 - 99 Beds	9	441	9,711	271
South Atlantic	199	34,756	1,162,760	23,991
500 + Beds	19	13,456	494,377	10,339
300 - 499 Beds	12	4,528	167,123	3,165
200 - 299 Beds	14	3,631	135,310	2,622
100 - 199 Beds	51	7,293	212,528	4,990
1 - 99 Beds	103	5,848	153,422	2,875
East North Central	154	19,900	560,928	11,928
500 + Beds	6	4,435	147,657	3,359
300 - 499 Beds	6	2,383	74,896	1,712
200 - 299 Beds	10	2,603	78,004	1,659
100 - 199 Beds	35	4,574	102,231	2,553
1 - 99 Beds	97	5,905	158,140	2,645

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1993 U.S. Hospital Universe By Hospital Type, Census Region, and Bed Size
Source: 1992 American Hospital Association Annual Survey of Hospitals

	Hospitals	Staffed Beds	Admissions	Census Beds
East South Central	159	21,588	651,279	13,348
500 + Beds	6	3,620	141,973	2,643
300 - 499 Beds	10	3,773	138,244	2,699
200 - 299 Beds	12	2,893	90,856	1,524
100 - 199 Beds	39	5,622	136,352	3,679
1 - 99 Beds	92	5,680	143,854	2,803
West North Central	300	20,692	423,341	11,867
500 + Beds	2	1,434	50,698	1,074
300 - 499 Beds	6	2,328	70,113	1,523
200 - 299 Beds	7	1,585	41,157	950
100 - 199 Beds	32	4,102	66,169	2,847
1 - 99 Beds	253	11,243	195,204	5,473
West South Central	310	26,800	855,111	14,967
500 + Beds	7	4,809	188,973	3,659
300 - 499 Beds	7	2,549	98,167	1,695
200 - 299 Beds	16	3,958	146,335	2,508
100 - 199 Beds	38	5,383	169,699	3,225
1 - 99 Beds	242	10,101	251,937	3,880
Mountain	119	9,403	259,778	5,735
500 + Beds	1	501	18,307	356
300 - 499 Beds	5	1,847	79,717	1,315
200 - 299 Beds	4	959	40,997	671
100 - 199 Beds	15	2,008	50,357	1,132
1 - 99 Beds	94	4,088	70,400	2,261
Pacific	151	20,066	748,351	13,790
500 + Beds	2	2,068	69,728	1,697
300 - 499 Beds	15	5,976	252,861	4,470
200 - 299 Beds	20	4,998	202,252	3,520
100 - 199 Beds	17	2,483	111,231	1,822
1 - 99 Beds	97	4,541	112,279	2,281

ARONOFF ASSOCIATES

Aronoff Associates is a consulting firm that specializes in the use of polymers in health care products. Since it was founded in 1982, Aronoff Associates has assisted major companies as well as smaller firms in the health care field on a wide variety of projects, often international in scope. Projects have ranged from conducting market research on a global scale, to inventing new products, to solving problems in product development.

Marvin S. Aronoff, Ph.D.
Principal

Prior to founding Aronoff Associates, Marvin S. Aronoff held several positions directly related to the development of products based on polymers. These positions included Research Chemist at the Pioneering Research Laboratories of E. I. du Pont de Nemours and Co.; Department Head, Israel Fiber Institute; and Division Director, Bioresearch (formerly affiliated with Pfizer). For the past eighteen years, the medical applications of polymers have been the primary focus of his work. Dr. Aronoff is the author of numerous studies for clients on the use of polymeric materials in medical products, and is an inventor of several health care products. He earned a B.S. in Chemistry at Queens College, New York and an M.S. and Ph.D. in Chemistry at Florida State University. He is a member of the American Chemical Society, the Society of Plastics Engineers (SPE) and the Medical Polymers Division of SPE.

PREPARED STATEMENT OF MARK REILY

Mr. Chairman and Members of the Subcommittee:

My name is Mark Reily. I am joined by Thomas, my 9 year old son, who is the reason I am here today. Together with my wife, Jane and three other children, we live in Houston, Texas. I am here to highlight from Thomas' perspective, as well as my own, how recent events, which have prompted the need for this hearing, could collectively result in an unacceptable situation that will destroy thousands of lives of those who are dependent on implanted medical devices in order to live. Thomas is one of those people.

When Thomas was 8 months old, in October 1985, he was diagnosed as having hydrocephalus, or "water on the brain." The so-called water of hydrocephalus is actually cerebrospinal fluid, a liquid produced in the brain that cushions it and the spinal cord from shock. In hydrocephalus the pint of fluid produced daily does not drain properly from the brain, thus accumulating abnormally in the head. The fluid builds pressure inside the head, like steam building inside a locked pressure cooker. If left untreated, it is a well-documented medical fact that the patient will initially suffer severe brain damage, become comatose and ultimately die.

Fortunately, a procedure has been developed and refined over several decades that can alleviate this condition. A shunt tube made of a soft and pliable plastic material called silastic can be implanted in the brain and drained in the abdomen to relieve the fluid buildup. Through a combination of improved surgical procedures, the availability of the finest appropriate Biomaterials for the shunts and technology such as MRI and CT-Scan equipment for diagnosis, the outlook for the hydrocephalic patient has greatly improved over the last decade. However, it is critical to note that these patients, primarily children, will require a shunt for their entire life. There is no cure for hydrocephalus. Further, each patient will inevitably require shunt revisions on a periodic basis, since despite the advances cited earlier, the shunt may malfunction due to clogging, infection or the child-patient out growing the tube's length. Thomas has had two shunt revisions since his original shunt was put in. Each year in the United States, there are approximately 75,000 shunt implant and revisions procedures performed.

Jane and I will never forget the Saturday in late October 1985 that we learned that Thomas had hydrocephalus. We initially were told that based on the level of fluid accumulated on his brain and the resulting pressure, he would surely have brain damage, probably severe. Surgery to place a shunt in Thomas was scheduled for the first thing Monday morning. The hours from late Saturday to Monday morning were the longest and darkest we have ever experienced. The thought of needing to wait even 1 day to have the surgery was almost unbearable, for each minute that passed the pressure was building in Thomas' head, which could further damage him. Finally, the time came to drive to the hospital, and this act lifted our spirits, for we were beginning to take action that would help Thomas. Modern medical technology would give Thomas a chance, and even in our moment of despair this fact was not lost on us. On Monday morning, Thomas received a shunt. Within hours he was showing improvement; his lethargy disappeared, he was alert, he smiled again for the first time in weeks and even stood up in his hospital crib. Within 36 hours we were back home with the "new" Thomas. How different the outcome would have been for Thomas that day without the availability of the medical device he so desperately needed.

In the months that followed we began adjusting to Thomas' condition emotionally. It is not easy to accept the fact that your child needs such a device as a shunt to live. But over the years we have come to accept that fact, and to be grateful for it. It is a cruel irony that as we have come to be at peace with his dependence on his shunt, there are events transpiring that would make his life saving device unattainable.

Six months after his original surgery, Thomas' shunt clogged and required revision. In the 6 hours that Thomas waited for his shunt revision surgery he became violently ill, vomiting continuously and finally becoming semi-comatose. Mercifully, his revision was successful and immediately he regained his old form, laughing and smiling while playing games in his hospital bed. Again, how different yet predictably sad and final would have been Thomas' fate without this medical device.

Thomas went 6 years before his next revision was required, in 1992. But the scenario was the same, as the shunt malfunctioned Thomas' condition deteriorated rapidly and relentlessly. When a new, properly functioning shunt was implanted, Thomas returned to his normal activities, working hard to overcome his learning difficulties, growing and maturing, and in a child's way striving to become a productive member of our society.

We had previously come to regard these shunt revision episodes as temporary mechanical digressions, sidelining Thomas for a week or so. If the lack of availability of required Biomaterials for Thomas' shunt become a reality, as it appears it might, for Thomas these episodes will instead become a nightmare, with predictable, permanent, devastating results.

As I reflect on Thomas' brief life I see a child who has already overcome a lifetime of medical difficulties. For in addition to the shunt implant and revision episodes I have detailed, Thomas was left with physical weaknesses from his hydrocephalus requiring extensive therapy. When Thomas was 6 he was diagnosed with a very rare seizure disorder called Landau-Klefner Syndrome, which left him unable to talk for over 1 year. But Thomas has endured and even prospered at times in the face of all these obstacles.

Early on, Thomas' mother and I went through a grieving process. We were grieving for the death of our vision of our perfect child. It was not until we let that vision go that we were able to see something much more beautiful, a young boy with an indomitable yet loving spirit who will not let his personal medical setbacks defeat him. I think that must surely be God's spirit living inside him.

So I stand before you today, as the guardian of that spirit, as Thomas' father, beseeching you to do everything in your power to ensure that the Biomaterials necessary for Thomas medical implant device be readily available and of the highest quality. For sometime in the future, perhaps next month or next year, Thomas will wake me in the middle of the night to tell me that his head hurts and that he thinks his shunt has broken. He will ask if we can to go to the hospital to get a new one right away. I pray that I will be able to give him the only acceptable answer.

Thank you.

PREPARED STATEMENT OF PEGGY A. PHILLIPS

Mr. Chairman, Members of the Subcommittee, my name is Peggy A. Phillips, Esq., and I am grateful for having the opportunity to appear before you today and share with you how a medical device known as an Automatic Implantable Cardioverter Defibrillator (AICD) has impacted my life.

The AICD monitors the heart and delivers a shock to the heart whenever the rhythm alters or stops.

Background

November 26, 1986, started off as a normal day. At the time, normal for me was getting up about 5:30 a.m., working all day as Chief of Congressional Affairs for the Air Force Surgeon General, going to law school in the evening, getting home about 10:00 p.m. and working until midnight or so on school work or office work. I was used to this pace because I also went to undergraduate school in the evening while working full time on Capitol Hill. I am sure this is similar to the schedule of a United States Senator.

However, on November 26, 1986, my life changed. I am told I collapsed as I walked from my office to my car. I stopped breathing. I had no pulse. I had no blood flow to my brain. I was clinically dead.

Fortunately, my car was parked next to a fire house and I immediately received CPR from the paramedics. I was "shocked" back to life with a portable defibrillator and taken to a nearby hospital.

This experience was very difficult to adjust to. I have been very healthy all my life. In fact, November 26, 1986, was only the second time in my life that I was a patient in a hospital. The first time was the day I was born.

Medical personnel performed numerous tests in an attempt to find something wrong with me. They found nothing. I was diagnosed as experiencing sudden death syndrome and sent home on medications.

But, life was not the same. I felt fine, but my family and friends treated me like a piece of fine crystal. I tried to understand what they were going through. After all, I did not remember how I looked with the tubes in my throat and nose. I did not remember the needles in my hands and arms. I did not remember being tied to the bed because I tried to escape from the hospital to go study for my law school exams.

However, I was determined to get back to my old routine. Then, on the morning of December 15, 1986, I experienced a slight chest pain while sitting in bed. As luck would have it, my mother was across the hall and immediately responded to my faint call. As she entered the room, my eyes rolled back and I slumped over. I had died a second time. Mom began CPR and called the Fairfax County Fire Station #18 Advanced Life Support Emergency Team.

I wish my mother could be here today. She is a very special lady and very determined. It is not often that a woman saves the life of the child she brought into this world. We should all have her strength. If anyone could convince you of the importance of finding some way of sheltering major corporations who make raw materials so others can advance medical science, she could.

The Advanced Life Support Emergency Team "shocked" me back to life and took me to a local hospital. More tests were conducted, but no cause for these sudden death episodes could be found. The doctors were hesitant to discharge me from the hospital. So, I reluctantly agreed to have an Automatic Implantable Cardioverter Defibrillator (AICD) implanted in my stomach.

Life With an AICD

Following a few minor adjustments, life with an AICD has not been much different than my life before the AICD. In preparing for this hearing, I wrote down the positives and the negative changes in my life since the surgery.

The negatives are somewhat silly——

- I had to get rid of 10 bikinis and 7 pair of skin tight jeans. You know, the kind you have to lie down on the bed to zip up.
- In addition, it took a while to get used to the scars, and
- I was self-conscious about the defibrillator showing when I wore certain clothes, like a swimsuit.
- Finally, it is inconvenient having to have the battery checked every two months and undergoing surgery every 3-5 years to have the battery replaced.

The positives changes since my surgery far outweigh the negatives——

- I am able to enjoy life without my family and friends worrying that I am going to die again.
- I completed my law degree and am now a member of three bars including the District of Columbia Court of Appeals.
- I am an active member of the Board of Directors of the Washington Civic Symphony.
- I try to exercise at least five days a week including step aerobics, jogging and weights.
- I especially enjoy running up the 120 or so steps on the West front of the U.S. Capitol building, and I have run in 5K races.
- I have been a part of the initial response team following some of the most devastating disasters in the history of the United States, including Hurricane Andrew and the Los Angeles riots. I was able to travel to these devastated areas without concern of an electronic malfunction, thanks to the AICD.

I know that I am lucky to be here today. I was fortunate on November 26, 1986, when that Air Force Sergeant brought me back to life. He later told me that I was his first save out of 10 victims.

I was fortunate on December 15, 1986, that my mother was across the hall. If she had been downstairs attending to my sister who was recovering from major back surgery, she would not have heard my call.

I was fortunate that the Fairfax County Fire Station #18 Advance Life Support Emergency Team brought me back to life.

I was fortunate that Doctors like Levi Watkins, Dean, Postdoctoral Programs, Professor of Cardiac Surgery, The Johns Hopkins University School of Medicine, and Michel Mirowski, Professor of Medicine, The Johns Hopkins University School of Medicine, were persistent in developing the AICD, even though they were criticized by their peers.

I was fortunate that there are companies like DuPont, Dow Chemical, and others that develop new raw materials used to advance medical science, and companies like Cardiac Pacemakers, Inc. that manufacture the AICD device in me.

Yes, Mr. Chairman, I know that I am lucky to be alive today. But, what happened to me could happen to you, or your loved one. Remember, I had no medical problems. There was no history of heart problems in my family. I was a good candidate not to have a cardiac arrest. But, it happened to me, and no one knows why.

Yet, the reason does not seem that important now as long as I have the AICD. However, I am concerned how much longer I will have that luxury when top suppliers of raw materials used in these devices are pulling out of the business.

As you can see, I am not a senior citizen. In fact, I hope to live another 50 or 60 years.

I have thought about how my life would be without an AICD. I think it would be similar to being in prison the rest of my life. And, I don't know if I could handle that.

Conclusion

Mr. Chairman, I consider what happened to me very personal, and I don't like to discuss it among strangers. I was told that I was one of the youngest patients to have the AICD implanted in this area. I am afraid that if people knew what I have been through, they would treat me differently, probably the way I was treated after my first episode of sudden death—like a piece of fine crystal. While I enjoy fine crystal, I would prefer to be compared to a tough diamond.

For these reasons, it was difficult for me to appear before you today. However, I feel very strongly about the need to examine the liability concerns of raw material suppliers.

I am sure you have heard some horror stories of patients reacting to particular raw materials, or medical devices that do not operate properly. When I worked for the Air Force Surgeon General, I dealt with many medical horror stories experienced by military personnel and their families. I have also read some of the legal cases filed against DuPont and the arguments presented by the plaintiffs.

However, this is not a perfect world. We need to find incentives to encourage the advancement of technology in the medical community, not discourage it. If Doctors Watkins and Mirowski did not pursue their idea of developing the AICD, I and 50,000 others like me around the world may not be alive today.

I applaud the major corporations like DuPont, Dow Chemical, and others who have done so much in the advancement of raw material science. And Mr. Chairman, I sincerely appreciate your taking the time to hold this hearing today and expressing your interest in this critical issue.

Mr. Chairman, that concludes my remarks for this morning. I will be pleased to answer any questions you or other Members may have.

PREPARED STATEMENT OF J. DONALD HILL, M.D.

The potential for a widespread shortage of polymeric raw materials used in medical device manufacturing is real. This view is supported by the accumulating evidence, reports and actions of the medical device industry in the United States and their suppliers of polymeric raw materials.

The exact extent of the problem is not yet available but, on a daily basis, it seems to be increasing without an alternative or practical solutions.

The predicted shortage results from a unique set of circumstances only possible in the litigious environment that has become a part of American society.

The volume, market value, and eventual profits of selling polymeric raw materials for use in permanent medical devices is comparatively small, measured against the risk of litigation and large financial settlements. In short, it is not a profitable business. As a result, many suppliers of raw material are getting out, and no one is stepping up to fill the market void.

The medical community can no longer treat this as someone else's problem. Our patients are going to be affected in as little as 18 months, when the supply of Dacron, for example, runs out. Other shortages will surface in 2–3 years.

My only goal today is to provide you with information on the direct effect these shortages will have on the public who require permanent implants which contain these materials, even though they may be present in minute quantities.

What is the direct impact on the American public in terms of types of implants and the number of patients involved?

Everybody will eventually be effected—you, me, your family and your community. In my own specialty of heart and vascular surgery, an estimated 700,000 patients per year needing implants would be directly effected and another 1.7 million indirectly. This includes the following:

—35,000 people per year needing artificial heart valves to replace their defective natural valves.

—140,000 patients per year needing pacemakers to maintain the rhythm of their heart.

—35,000 patients per year needing implantable defibrillators to resuscitate them from sudden cardiac arrest occurring outside a medical care setting.

—230,000 patients per year needing vascular grafts to replace obstructed and diseased arteries throughout their body.

There are hundreds of temporary devices not used for long term implants but will nonetheless be caught up in the shortage of raw materials. These include 1 million patients each year having diagnostic heart catheterization, 331,000 patients each year having angioplasty, a procedure that dilates the small arteries of the heart. Lastly, 342,000 patients who undergo open heart surgery every year are impacted.

These patients require a heart-lung machine for temporary support while the corrective surgery is being done. A heart-lung machine is fabricated with up to 15 polymeric materials.

The vast majority of these patients return to a productive life. I am confident that in this room alone there are people or members of their families who have been or will be the beneficiaries of some of these therapies.

Dr. Bernard Stulberg will report to you on the bone and joint implants in orthopaedics.

In brain surgery, 75,000 life saving ventricular shunts are implanted each year. Many of these patients are young children, who go on to live normal and productive lives, who would otherwise be institutionalized for life.

In urology, a variety of 2500 incontinence devices and 50,000 penile implants are used each year.

Your sight—the simple act of being able to see where you are going and what you are eating. More than 1 million cataract implants per year for opacified lenses, 3,000 shunts for patients with glaucoma—abnormal high pressure in the eye; retinal detachment a misfortune that strikes young and old—25,000 per year.

These numbers are sobering. Many of my colleagues in my own specialty of cardiac surgery have dismissed this problem as impossible because of the huge effect it would have on patient care. They cannot conceive of any scenario in which this could come to pass. Nonetheless, it is happening.

What are the cumulative effects of the shortage? Certain patients will die in large numbers. Other patients will not die, but will have unnecessary pain and suffering and a poor quality of life.

The cost of health will go up. Physicians will continue to treat their patients but will do so with less effective, more extensive technology reintroduced from the past.

We will have to spend 10 years searching and developing new biomaterials only to have them face the same liability risks that exist today. Capital for innovation will be in short supply because medical device manufacturing will be viewed as an industry that has an unaddressed, unique societal problem—deep-pocket motivated litigation.

Large companies who are able to pay the costs of indemnifying polymeric raw suppliers will gain a monopoly of the market place that will be more valuable than a patent position. Most device innovation originates in small companies, so the opportunity to extend the art and craft of medicine would suffer or come to a standstill, as widespread competition in the marketplace winds down.

The medical community has no motive to create an artificial crisis, as has been suggested. Our desires are twofold. First we wish to effect a solution that will not interrupt the ready supply of currently available high quality implantable medical devices for our patients. Second, we wish to promote the innovation of worthwhile, new devices.

It is certainly true that need spawns innovation. But since the problem we face is societal in nature, any need driven technical solution would face the same product liability dilemma. Substitutes are not the solution. They are a Band-Aid. There must be a balance struck between protecting the consumer against poor products and not penalizing the rest of society, who need medical implants to enhance both the longevity and quality of their lives. A legitimate business decision by the manufacturers of raw materials used in medicine, which is often a small fraction of their overall business, is now destined to have a huge effect on the public. How far back in the chain of command does the responsibility to the patient lie? There is something wrong with a societal process which results in the outcome we now have.

Solutions are not easy, but the medical community is unified in their support of maintaining the authority and thoroughness of the FDA in their role of controlling the safety and effectiveness of any device used in patients. We applaud any improvement in the FDA process but would resist short cuts in the approval process.

We ask the members of this Committee and the Congress to be creative in a solution that will serve all parties. We ask, further, that they act quickly because we do not have time on our side. Thank you.

PREPARED STATEMENT OF BERNARD N. STULBERG, M.D.

I am pleased to say a few words to you on behalf of the American Academy of Orthopaedic Surgery. Our specialty deals with medical care of the musculoskeletal system, and as such has more than a 40 year history of using implantable medical devices. Our field has been characterized by intense basic and clinical research into the performance of such devices, and has been able to substantially improve the quality of life of our patients because of these devices. I believe that we can offer

a perspective to this recent concern relating to the availability of basic materials for the manufacture of devices that will be used for biological implantation, and I hope that it might prove of benefit in your deliberations. There are three basic messages from this perspective:

1) Any implantable device that is subjected to stress has the potential to fail over time. This is particularly true for devices used in load bearing applications;

2) The failure patterns of devices used in load bearing capacity is usually multifactorial, involving varying contributions from device related factors, technical factors of implantation, and biological factors, including patient usage; and

3) The risk to our patients, our specialty, and to the American manufacturers of the products we use is substantial if we equate device failure with inadequacies of the base materials incorporated into these devices. Until such time as new mechanisms for device evaluation prior to and after implantation are developed and applied routinely, statutory protection will be necessary to protect suppliers of base materials. These new mechanisms will require the combined efforts of scientists, manufacturers, regulatory agencies and clinicians to establish processes of evaluation that limit the exposure of patients to what ultimately become poorly performing implants.

In short, this perspective will suggest that there is no material implanted in a patient that could not fail eventually. These failures are not necessarily the result of material problems, but are intricately related to the design of the part in which the material was used, the way that the device was implanted in the patient, the manner in which the patients system has adapted to the device, and the level of use to which that device is subjected. To lay blame to the material alone underestimates the problem substantially.

While the basic biomaterials pulled off the market by DuPont and Dow Corning have only a small impact on the orthopaedic marketplace today, we do have a number of materials used for a variety of applications that could be placed in similar jeopardy if the suppliers of these materials chose to withdraw from the medical marketplace. The most obvious of these materials is the polyethylene component of total joint replacement prostheses. Approximately 450,000 patients per year undergo hip or knee replacement surgery in the United States each year. Each of these devices has a component that is fabricated from a high strength metal, which mates with a surface of ultrahigh molecular weight polyethylene (UHMPE—"polyethylene").

I would like to use the application of materials in devices used for total hip replacement surgery as an example of our triumphs and failures, and the impact of the basic materials. This surgery is used to treat end-stage arthritis of the hip joint, fractures of the upper part of the femur, problems related to blood flow abnormalities of the hip, tumors involving the hip joint, and a host of other applications. It provides predictable pain relief and substantial improvement in function of the joint and of the patient, and allows the restoration of a patient's quality of life. This operation is performed over 250,000 times per year in the United States, and when combined with other joint replacement procedures, has spawned a $10 billion industry. The operation first came to this country in 1968.

The hip joint carries forces of approximately 3 to 5 times body weight with each step that an individual takes. The average individual walks on his (her) hip approximately 1 million times per year. Thus it is easy to see that devices used to replace this joint are to be subjected to substantial forces over time. While in the early years of joint replacement surgery we experienced some breakage of devices, a number of other mechanisms of device failure have been identified. A large majority of these mechanisms of failure are determined from careful analysis of the concepts used to design the implant, the processes involved in manufacturing the device, the clinical environment and clinical performance of the device when it was implanted, and a careful analysis of the retrieved implant once it is removed, either for failure or in post mortem examination. This entire process has been called the "life cycle" of the implant, and is only recently receiving careful attention from clinicians and scientists.

There may be three broad categories that can be used to describe device failure. These are: 1) factors related to the device itself, which include its design and the materials of which it is made; 2) factors related to the patient in whom it is implanted; and 3) factors related to the implantation of the device.

Currently of significant concern to the orthopaedic community is the issue of wear of the UHMWPE. When hip replacement surgery first came to the United States in 1968, the devices used were of stainless steel stems mated with socket devices of all polyethylene. These were anchored with bone cement. With time, we found that certain stems devices were not strong enough, and new metal alloys and processes for manufacturing were devised; we found that cement could fragment and cause debris leading to excessive bone loss; and we saw wearing of the polyethylene.

We moved to newer devices, requiring substantially greater sophistication in manufacturing, that would address these problems. New processes providing alternatives to the use of cement, required mechanisms to attach devices directly to bone, required improved metallurgical processes, and led to newer approaches to using polyethylene. These approaches have resulted in markedly improved devices that have found usage in an expanding number of circumstances, many of which place even greater stresses on devices than have been previously felt to be reasonable—most notable is that in a famous baseball player. Polyethylene is still an extremely important component of each of these devices. Our attempt to move to new approaches for bone attachment appears to have had a negative impact on the performance of this polyethylene. In one series of patients, we have been seeing evidence of wear of a particular device in as many as 50 percent of patients by 7 years—a rate of wear that is nearly twice as fast as what we were previously experiencing. Specific features of this wear were the thickness of the polyethylene used in the device, the size of the patient, the activity level of the patient, and the angle of implantation of the device. To blame this failure rate on the base material, and to hold the suppliers accountable, would not be accurate nor would it be in the best interest of our industry.

At present, the supply of polyethylene is from two sources. The percentage of polyethylene that these manufacturers produce that goes to the medical marketplace represents approximately ½ of 1 percent (0.5 percent) of its total output. If for liability reasons, these manufacturers were to withdraw from the medical marketplace, we would be forced to return to approaches used before 1968. This would have the impact of undermining the $10 billion industry associated with joint replacement activity, driving most of the industry offshore or making us entirely dependent upon manufacturers outside of the United States.

A good deal of research effort, in time and money, by academic centers, orthopaedic manufacturers, and materials scientists have been focused upon understanding the mechanisms of polyethylene wear, the consequences of wear, and the design issues of the devices that can decrease the likelihood of wear. All efforts at research are directed at improving the performance of the material. Only recently are scientists and manufacturers looking for alternative materials, an expensive process that could take years to develop and bring to the marketplace.

The point which we wish to make is that none of the materials we use is perfect. As we identify problems in certain applications of these materials and address them directly, we run the risk of compromising performance of other aspects of the devices. There is likely to be either a biological or biomechanical consequence (or both) to each material we use in a biological environment. It is clear that there are factors relating to device failure that physicians may not be able to completely control—the biological factors such as infection, or rejection. But there also are factors that clearly can be controlled by the physician—such as the implantation of appropriate components in the proper position; and by the manufacturer, such as the quality of the material selected and the proper shaping and characterization of the materials as they are fashioned into devices. Each or these areas has an impact on how that material will perform once it is implanted.

We believe it is important to identify those areas of the medical community that have this precarious relationship of high risk with low return, and to provide them with statutory protection. It will be similarly important to work toward newer methods to predict and injure safety or devices over extended periods of implantation, and to provide a cooperative regulatory environment that stimulates their development.

Thank you.

PREPARED STATEMENT OF PIERRE M. GALLETTI, M.D., PH.D.

Thank you for the opportunity to address a problem of commerce which is bound to have a major, deleterious impact on patient care in the U.S. if not properly attended to. My name is Pierre M. Galletti from Brown University in Providence, where I am a University Professor and Professor of Medical Science and Head of the Artificial Organs, Biomaterials and Cellular Technology group. I obtained a M.D. degree in 1951 and a Ph.D. in Physiology-Biophysics in 1954 from the University of Lausanne in Switzerland. Since 1957, I have been involved in artificial organ and implant research first at the Cedars of Lebanon Hospital in Los Angeles, then at Emory University in Atlanta and lastly at Brown University.

I speak here as President of the American Institute for Medical and Biological Engineering (AIMBE), an umbrella organization which includes 320 elected fellows—the senior scientists in the field from academia, industry and government—46 uni-

versity based programs in bioengineering—and 12 specialized bioengineering societies with about 20,000 members. AIMBE was established for the purpose of unifying the bioengineering community and promoting the engineering approach for enhancing health and quality of life through innovation and appropriate use of technology. AIMBE's focus is on the development of public policy. We have concluded that the recent embargo on materials used for the fabrication of implantable devices is a major public policy issue which threatens the care of critically ill patients, endangers innovation and scientific progress in basic and clinically oriented research, and affects competitiveness and employment in an industry segment in which the U.S. currently has the undisputed leadership.

AIMBE's perspective on the Biomaterials Crisis is expressed in a letter to the Editor of *Science* magazine published in today's issue of that journal. I quote:

"A recent review in *Science* (1) pointed out significant opportunities in the creation and characterization of biomaterials which are essential components of therapeutic implants. As pointed out in that same review, materials which are reasonably biocompatible with use in the human body (e.g. polyester for vascular grafts, polyurethanes for pacemaker leads, silicone elastomers for hydrocephalus shunts) are becoming increasingly difficult to obtain from primary producers, and may soon disappear altogether from the U.S. scene. The reason is that chemical companies such as DuPont, Dow, Dow-Corning and others have determined that unpredictable and excessive liability costs of doing business with manufacturers of implantable medical devices no longer allow unrestricted sale of standard polymers to these customers. Under current U.S. product liability laws, any remote supplier of commodity materials can be joined in lawsuits involving medical products which are alleged to have failed unexpectedly, not lived up to expectations, or caused complications.

Since the sales of such materials represent but a tiny fraction of the business of chemical companies, but account for a major part of their liability or legal costs, it is more expedient for them to opt out of the medical device market.

This embargo, which already affects the main sources of fluorinated polymers (e.g. Teflon®), polyacetals (e.g. Delrin®), silicone compounds, polyurethanes and polyesters (e.g. Dacron®), is progressively extending to other elements of medical devices, i.e., the small, but essential amount of PTFE powder which enters into the fabrication of batteries for cardiac pacemakers. or the electric components of such devices, as well as to the specialty metals used for pacemaker casings and joint replacement prostheses. The resulting crisis could bring to a halt the fabrication of implantable devices in the U.S., resulting in a shortage of widely-used, FDA approved devices on the U.S. market, inadequate treatment for thousands of patients, and the loss of jobs in a major sector of U.S. industry. Other potential consequences include a shortage of materials for artificial organ and cell transplantation research, the loss of engineering and medical experience as material fabrication and clinical trials are shifted abroad, the closing of career opportunities for graduates of U.S. training programs, and a diminished incentive to develop new materials since the know-how of industry is needed to assure quality-controlled production.

This is a complex situation which increasingly resembles the crisis already faced by the U.S. small aircraft manufacturers, most of whom have gone out of business or into bankruptcy because of liability losses. The same fate threatens the U.S. medical device industry. NIH leadership is needed in addressing this issue and in directing research to establish a scientific base for technological advances in the field of medical devices and implants. The Health Industry Manufacturers Association (HIMA) is coordinating efforts with the FDA to establish "equivalence" criteria for substitute materials in shortage areas, and keep critical devices on the market (2).

In the short run, the most effective remedy would be to change tort law to bar product liability claims against remote suppliers of "off the shelf" commodity materials and components of devices which have received FDA approval. The entire liability burden would then fall on the device manufacturer, who could decide whether or not to market a device.

Better solutions may be generated through discussion with all involved parties. However a temporary resolution is urgently needed if we are to avoid a shortage of chronic implants for critically ill patients."

I would like now to dispel some common misconceptions that relate to the field of biomaterials for chronic implants, and conclude by suggesting some steps that could be taken to alleviate the impending crisis.

First some facts to keep in mind when addressing this issue. The overwhelming majority of materials incorporated into chronic implants are standard, commodity plastics, metals or ceramics widely used in non-medical products. The term biomaterial is only justified inasmuch as these materials meet definite, stable specifications and are processed and potentially modified to fabricate implantable or blood contacting devices. Therefore clinical biocompatibility characterizes the entire,

assembled device and cannot be assumed from its constituent materials. Second, there is no such thing as a universally biocompatible material for all applications. The very same polymers which function satisfactorily in one type of implant (e.g. the teflon mesh in the suture ring for a cardiac valve) can prove disastrous in another context (e.g. the teflon articular surface of a temporo-mandibular joint). Third, the quality and reproducibility of polymeric materials used for chronic implants (e.g. Dacron polyester for vascular grafts) is directly related to the amount produced and the experience of the manufacturer. Since the quantities used for medical devices are vanishingly small compared to other industrial applications, it is not surprising that reliable materials have largely been obtained from major suppliers of chemical products developed for non-medical uses. It is not impossible to fabricate reliable polymers on a small scale, but the cost will be orders of magnitude higher than is presently the case. Finally, we should not forget that the body environment is warm, humid and corrosive, and that under such harsh conditions some degradation is unavoidable in chronic implants. Unrealistic expectations all too often cloud our evaluation of replacement parts for the human body. Wear and aging affect the implant as much as they affect the person who receives it. The concept of a permanent, failure-proof medical device is an ideal to strive for, but for the moment it remains unobtainable in 100 percent of the cases. In this regard, it is paradoxical that we should hold chronic implants to a higher standard than drugs, where side effects and failure to achieve the desired effect are, within limits, broadly accepted.

What recommendation can I formulate to meet the biomaterials crisis? Ideally, measures should be taken to convince remote suppliers of commodity materials or components for medical devices to keep them available to the U.S. medical device industry. This may require a narrowly defined change in the law to provide relief or remedy for ultimate liability claims against providers of standard, off-the-shelf elements of approved devices.

Second, the National Institute of Standards and Technology could undertake collaborative programs with industry to target R&D and establish a strategic reserve to insure the availability of materials which are essential for the manufacturing of medical devices and which have proven life-saving for critically ill patients. This would establish reliable sources of standardized, specifications-meeting, quality-controlled commodity polymers designed to interact with blood or other body tissues.

Third, the Food and Drug Administration, in concert with other Federal agencies, should build on the data bases which will result from the federally mandated medical device tracking system to develop a National Implant Data Retrieval and Analysis structure. Such information will allow statistically valid evaluation of chronic implants, and the materials and components thereof, and provide a perspective on patient-related versus device-related failures, which are often confused.

Lastly, the National Institutes of Health should prioritize programs that expand the science underlying the clinical use of chronic implants. This would include the mechanisms of degradation of biomaterials, the fundamental processes in the interactions between materials and body tissues, the individual and species-specific differences in bioreactivity to materials, and the development of non-invasive implant monitoring techniques applicable to man.

Hopefully out of the present crisis will come new insights into the success or failure of implants, better rehabilitation of critically ill patients, and preservation of therapeutic approaches for which there are currently no substitutes. Thank you for the opportunity to express these thoughts to you today.

PREPARED STATEMENT OF M. KRISTEN RAND

Mr. Chairman, members of the Subcommittee, I am Kristen Rand, Counsel in the Washington Office of Consumers Union, the publisher of *Consumer Reports*. Thank you for the opportunity to share our views regarding medical device materials suppliers. I am testifying today on behalf of Consumers Union (CU) Public Citizen's Congress Watch and Consumer Federation of America (CFA).

Consumer access to safe, effective medical devices is of great concern to all of our organizations. We recognize that many people's health and even lives depend on the continued availability of well-designed and safe medical devices.

We are also aware that device manufacturers complain that many suppliers of raw materials are refusing to furnish substances critical to the production of a variety of medical devices.

If there is a danger that consumers will be denied access to safe medical devices because of a lack of availability of raw materials, that is indeed a problem. Before we hurry to implement changes that might affect device regulation, however, sev-

eral key questions must be answered: (1) does a problem really exist? (2) if it does, what is its scope? and (3) what remedy, if any, is warranted?

We appreciate the opportunity to be here today not only to present the views of our organizations but also to help accurately evaluate the situation.

Particularly with regard to medical devices, our organizations always proceed with extreme caution. The past few decades are replete with examples of manufacturers making assurances to Congress and the public that a particular device is safe but claiming that its availability is nevertheless threatened by the product liability system. Almost without fail, we later discover that the device at issue is unreasonably dangerous or defective. This experience has forced us to be skeptical and not accept at face value claims made by the device industry and manufacturers. One example of proponents of liability "reform" making misleading claims about the safety of a device is the Vitek jaw implant.

In 1990, Malcolm Skolnick, a professor of biophysics at the University of Texas testified before the Senate Commerce Committee that jaw implants manufactured by Vitek, Inc. and used to treat a condition known as temporomandibular joint dysfunction were safe but that Vitek was in danger of being driven out of the market by frivolous the product liability suits. When we investigated this claim, however, we discovered that the FDA had, a month prior to Professor Skolnick's testimony, required Vitek to distribute a letter to oral surgeons warning of the device's tendency to fragment. FDA later issued its most stringent recall order for the device. In addition, a Subcommittee of the House Government Operations Committee uncovered evidence suggesting that there were serious problems with the Vitek implant as early as 1986. The late Congressman Ted Weiss who chaired hearings on the issue concluded, "There is evidence that the overwhelming majority of the grafts and implants will eventually fail if they haven't already."[1]

Incidents such as the Vitek implant force us to very carefully evaluate any claims made by medical device manufacturers about the effects of liability on their products.

From our perspective, it is imperative that any fix designed to ensure the availability of devices not end up hurting consumers more than helping them. At this time, since there is no specific proposal from those seeking relief it is difficult for us to determine if we could reach an agreement regarding a specific remedy, but we are interested in reviewing alternatives that may be offered to resolve the issue. Meanwhile, we can identify some proposals which have been discussed in the context of medical device availability which we strenuously oppose.

In general, we are opposed to changes in the civil justice system that would result in diminution of the rights of consumers to recover fair and adequate compensation through the courts.

Limitation on Joint and Several Liability is Not the Answer

The Health Industry Manufacturers Association (HIMA) supports the limitations on joint and several liability contained in S. 687, the "Product Liability Fairness Act." We find their stated position on the joint and several provision somewhat confusing. HIMA has stated that raw materials suppliers "may be brought into litigation and held liable for damages, even though the supplier has no direct role in the material's ultimate use as a biomaterial. As a direct result of this predicament, three major raw materials suppliers recently announced that they would limit or cease altogether their shipments to medical device manufacturers."[2] We find this fear on the part of materials suppliers odd in light of the fact that courts are routinely dismissing suits against suppliers who sell components to manufacturers that make devices later found to be defective. For example, a Federal court in Hawaii recently granted summary judgment to Du Pont and Dow Corning in a case alleging injuries from an implant manufactured by a bankrupt company. The court refused to hold the suppliers liable where an inherently safe component part is used in a defective end product.[3] Other courts have dismissed similar cases.[4] All of these cases involve Dow Corning and/or Du Pont supplying materials for the Vitek jaw implant discussed above. Manufacturers are clearly not in danger of being held lia-

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[1] Human Resources and Intergovernment Relations Subcommittee, Committee on Government Operations, U.S. House of Representatives, June 4, 1992.

[2] HIMA written testimony before the House Subcommittee on Commerce, Consumers Protection and Competitiveness, February 2, 1994.

[3] *Kealoha* v. *E.I. du Pont de Nemours & Co.*, DC Hawaii, No. 92–00282, February 24, 1994.

[4] See e.g. *Bond* v. *E.I. duPont de Nemours & Co.*, Colo Ct App. No. 92CA0624, June 3, 1994 and *Lamontagne* v. *Du Pont Co., DC Conn*, No. 3:91 (CV 142, September 29, 1993.

ble merely for supplying safe components even when the devices into which they are incorporated are found to be defective.[5]

Although courts are dismissing cases against component manufacturers where there is no evidence that the suppliers know that their materials were being used in a dangerous manner, we feel strongly that the potential for liability must remain where a defendant does know that a manufacturer is using a component in an unsafe manner.[6] In addition, it is important to try not to encourage manufacturers to turn a blind eye should suspicions be raised that its components are being used in an unsafe manner.

Blanket protection for manufacturers of raw materials or device components is inappropriate and unacceptable. Determining whether a particular component manufacturer has sufficient knowledge of a hazardous use of its components is a fact specific inquiry that is best made on a case by case basis.

A Bar On Recovery of Punitive Damages for Devices Approved by FDA is Not the Answer

HIMA has also expressed support for the FDA defense contained in S. 687. This provision would bar recovery of punitive damages in a case involving a drug or medical device approved by the FDA, unless there was fraud perpetrated on the agency. Our organizations are adamantly opposed to this comprehensive protection for medical devices from liability for punitive damages. History clearly demonstrates that despite the appearance of a thorough and extensive regulatory regime, the FDA has not been able to adequately protect the public from manufacturers who knowingly or recklessly market dangerous medical devices. There are far too many examples of instances where FDA could not by itself adequately protect the public from dangerous, defective medical devices.

Examples of dangerous devices that managed to get through the FDA approval process include:

• *Injectable bovine collagen.* In 1981 the FDA approved bovine collagen as a device. FDA accepted the manufacturer's clinical data despite serious gaps in the information including: lack of adequate follow-up; lack of representative clinical subjects for the type and age of the population that would use the product; and FDA failure to review safety information prior to pre-market approval. Subsequent to pre-market approval, adverse reactions apparently associated with the product began to occur. The reactions included serious autoimmune diseases. In 1991, FDA Commissioner Kessler acknowledged that there was an association between bovine collagen injections and autoimmune reactions.

Meanwhile, the manufacturer engaged in continuing violations of FDA regulations including underreporting of adverse reactions, unreported label changes and making misleading claims of efficacy.

It is worth noting that the manufacturer of bovine collagen actively sought approval of the substance as a medical device rather than as a drug. A member of the board of directors of the manufacturer testified in a deposition that the time-consuming drug approval process could have damaged the firm's chances to market the product.[7]

• *Theratronics radiation equipment.* FDA approved the Therac 20 Linear Accelerator in 1977 for use in the treatment of cancer. In 1983, the company introduced the Therac 25. In 1986 and 1987 the device was associated with three deaths of patients undergoing cancer therapy. When the FDA undertook an internal review after the three deaths, the agency could not locate any record of the device's pre-market approval. Apparently, the company had submitted an application, had received approval but FDA had failed to keep records of the approval.

Between 1984 and 1988, five deaths were associated with malfunction of a Theratronics linear accelerator and a number of incidents associated with over- or underexposure to radiation were reported. It was not until 1991, however, that FDA prohibited the importation of the device. The Subcommittee on Oversight and Investigation of the House Energy and Commerce Committee[8] determined that in the

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[5] Moreover, in all of the cases cited above, the manufacturer of the defective device, Vitek Inc., was bankrupt. This fact argues contrary to manufacturers' often repeated concern that innocent "deep-pocket" defendants are forced to pay when other culpable parties are judgment proof.

[6] This is the law, for example, under the Connecticut Product Liability Act. This was the rule applied in *Lamontagne, supra.*

[7] Deposition of Terry Knapp, MD in *Ramey* v. *Collagen Corp.* (Texas).

[8] *"Less than the Sum of Its Parts: Reforms Needed in the Organization, Management and Resources of the Food and Drug Administration's Center for Devices and Radiological Health."* A report of the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, May 1993.

case of Theratronics, FDA had failed to (1) ensure that the manufacturer had demonstrated either safety and efficacy or substantial equivalence before premarket approval; (2) take timely and decisive action when problems were exposed; and (3) conduct necessary inspections upon requests of the agency's own inspectors. As a result of these failures, the Subcommittee report concluded, "a machine was allowed on the market that actually killed patients seeking to benefit from it, and that may have been ineffective in treating life-threatening diseases."

Unfortunately, there are many more examples we frequently cite including the Bjork-Shiley heart valve, silicone breast implants, and Copper–7 IUD illustrating FDA's inability to adequately police the medical device industry and to provide assurance that medical devices are safe for their intended use.

Deficiencies in FDA oversight of the medical device industry are acknowledged by the agency itself. In November of 1993, the agency proposed to make medical manufacturers follow quality standards during the design phase as well as during production. In announcing the proposal, the agency cited a figure blaming design flaws for 44 percent of problems that force manufacturers to recall defective products.

Conclusion

Currently, Federal regulation of the medical device industry is simply inadequate. Civil liability for manufacturing and marketing dangerously defective medical devices provides an irreplaceable incentive in making medical devices safer and in ensuring that consumers who are injured by defective devices are compensated. Therefore, our organizations feel very strongly that any action designed to remedy what problems medical device manufacturers may be experiencing with suppliers must not consist of liability shields.

Our resistance to remedies involving changes in the tort system should not be read as refusal to engage in discussions of other types of proposals. If we are satisfied that a real problem does exist, we would be happy to explore remedies that do not limit consumers rights to recover when they are injured by dangerous medical devices.

Some options that we are willing to explore with the manufacturers could include indemnification for litigation expenses or government subsidies for production of vital raw materials.

Thank you.

PREPARED STATEMENT OF BARBARA A. JACOBY

Today I come before you the fortunate beneficiary of the latest in biomedical development for cardiovascular application. I say fortunate because through the combined efforts of engineering, medicine and materials, treatment specific products are created to repair/replace malfunctions in the body. Few outside the biomedical field fully appreciate the role raw materials (plastics, silicones, metals and ceramics), play when used to make the component parts that become the products to fix our bodily malfunctions. Further, they have little empathy for the time and cost necessary to run biocompatibility and clinical trials plus the special training necessary prior to general release.

I speak from experience both as an "active" patient/consumer and as an applied development engineer. I practiced a heart healthy lifestyle and had few of the typical heart disease candidate characteristics. I followed a nearly fat free vegetarian diet, never consumed alcohol or tobacco, exercised regularly and tried to relax. Though my hypertension was controlled with medication and my cholesterol was extremely low, my disease progressed undetected. Initial diagnosis of arterial blockages followed swiftly after mild mid-chest discomfort and three incidents of unstable angina (chest pain at rest and/or during sleep). The attempted percutaneous transluminal coronary angioplasty (PTCA), commonly referred to as the "balloon", failed resulting in an extremely large blood clot and total blockage of the right coronary artery (RCA). During this interventional procedure my vital signs turned negative and I left the catherization lab with several high tech biomedical devices to protect and stabilize my heart. I am most thankful for the temporary pacemaker, the intraaortic balloon pump and intracornary Urokinase (the expensive medication that dissolves blood clots quickly and save many lives) available to me.

My options, I was told, now were 1) aggressive medical therapy to control the heart's rhythm, spasms, and angina with considerable restriction physically or 2) coronary artery bypass grafting (CABG) otherwise known as "bypass" which is an invasive open heart, major surgery procedure under general anesthetic. I elected to follow the medical therapy program while investigating the current status on interventional techniques. As my angina worsened, the cardiologist insisted "bypass" was my only option and to forget the interventional devices for they were "many years

down the road". I chose to wait and asked my internist to be alert for less invasive options than bypass for I felt it was much too dangerous for a single closed vessel disease in a middle aged person (otherwise reasonably healthy). I must add there exists a family history of heart attack and sudden death. My father died in 1976 following his third heart attack. He suffered extreme angina in the 5 years prior to his death. The only relief he had was nitroglycerin tablets to abate the pain of angina. I marvel at the range of choices available to treat heart disease today to help us live better quality lives even with infirmity.

After a period of 14 months I connected with a major research center approved to run clinical trials using investigational revascularization procedures (i.e. using laser and/or atherectomy catheters to open obstructed arteries). During a second cardiac catheterization I learned my heart's arteries were heavily calcified (something like the mineral deposit that forms in your plumbing when you have hard water). It became apparent I would need to return when the rotational blade atherectomy device was reapproved for clinical trials. Without hesitation I said "Put me on the list". It made sense to me, for the rotating blade cuts away inelastic blockages at a high rate of speed reducing it to fine particles smaller than a red blood cell. Seven weeks later the right coronary artery was opened and has remained so to date. Six months ago the same procedure was used to open my left anterior descending artery (LAD) commonly known as the widow(er) maker. I continue to follow a total lifestyle heart healthy program, but one cannot deny the impact of genetics and other biochemical factors.

In closing, CHOICE in medical treatment and the availability of defect specific biomedical products is what I have had and would like to have in the future. For doctors and patients to have choice, we must NOT permit development of biomedical products to regress and curtailment of critical raw materials will certainly reverse the United States' sophisticated medical devices industry. Patients must be willing to weigh the risk of bioincompatibility with that of life threatening conditions and assume greater responsibility. Who knows what the future holds for YOUR body in the coming decade? Will you have choices?

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REVIEW ARTICLES

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JANE F. DESFORGES, M.D., *Editor*

ABDOMINAL AORTIC ANEURYSM

CALVIN B. ERNST, M.D.

MODERN treatment of abdominal aortic aneurysms began in Paris on March 29, 1951, when Dubost performed the first successful aortic resection for aneurysm.[1] The following year American vascular surgeons duplicated Dubost's feat and established aortic reconstruction as the treatment of chnice. Today, few dispute that all aneurysms of a predefined size should be repaired unless strong contraindications are present.

This review addresses the contemporary knowledge and management of infrarenal abdominal aortic aneurysms. It does not discuss infected aneurysms, thoracoabdominal and pararenal aneurysms, anastomotic aneurysms, or aortic dissections. An aneurysm is defined as a focal dilation of the aorta involving an increase in diameter of at least 50 percent as compared with the expected normal diameter.[2]

THE MAGNITUDE OF THE PROBLEM

Abdominal aortic aneurysms were responsible for 14,982 deaths in the United States in 1988 among people 55 years of age or older.[3] Of these deaths, 9874 occurred in men and 5108 occurred in women. Surgery is the only effective treatment, and in 1988 40,000 aortic reconstructions for aneurysms were performed in the United States.[4] Most reports cite dramatic differences in mortality rates between elective and emergency operations, but these data do not reflect just how lethal abdominal aortic aneurysms are. Up to 62 percent of patients with ruptured aneurysms die before reaching the hospital.[5] When these prehospital deaths are counted, the overall mortality rate after rupture may exceed 90 percent.[5-7] This formidable clinical challenge is only increasing as the population ages.

The incidence of abdominal aortic aneurysms may be rising. Two reports from the Mayo Clinic document a threefold increase from 12.2 per 100,000 to 36.2 per 100,000 during the three decades from 1951 through 1980.[8,9] More aneurysms of all sizes were diagnosed from 1971 through 1980 than in the previous two decades, which suggests a real increase in incidence regardless of technological improvements in detection. The increasing median age of the population contributes to an increasing incidence. A Swedish study conducted from 1958 to 1986 documented that the incidence among men increased rapidly after the age of 55, with a peak of 5.9 percent at the age of 80.[10] Among women, the incidence increased rapidly after the age of 70, with a peak of 4.5 percent at the age of 90. The autopsy rate in the study was 83 percent.

Aside from the cost in lives, ruptured aneurysms impose an increasingly onerous financial burden on hospitals. On the basis of cost-reimbursement data for diagnosis-related groups, one study documented that emergency operations resulted in a mean financial loss to the hospital of $24,655 per patient.[11] Another study estimated that 2000 lives and $50 million could have been saved annually had aneurysms been treated before rupture.[12]

PATHOGENESIS

Abdominal aortic aneurysms have usually been characterized as atherosclerotic, but this view of their pathogenesis is a restricted one. There is little support for atherosclerosis as the unitary cause in view of recent observations that suggest a multifactorial causation. Consequently, it would be more accurate to designate most aneurysms as "nonspecific."[2] As yet, no unified concept of pathogenesis has emerged, but several factors appear to have an important role, including familial clustering, genetically predisposed and acquired biochemical alterations in the structural matrix of the aortic wall, and hemodynamic mechanical factors.[13-29] Enthusiasm for these recent observations must be tempered by the realization that additional causative factors in the genesis of aneurysms will undoubtedly be elucidated. Pathogenesis is not simply a complication of atherosclerosis, however. Atherosclerosis may actually represent a secondary, nonspecific response to vessel-wall injury.

NATURAL HISTORY AND THE RISK OF RUPTURE

Estes[30] and Szilagyi et al.[31] attempted to define the natural history of untreated abdominal aortic aneurysms before aortic reconstruction. The five-year survival of untreated patients in these two studies was 19 and 17 percent, respectively; 63 and 35 percent of the deaths resulted from rupture. Both clinical studies were retrospective and included selected patients from referral-based practices. The true natural history of abdominal aortic aneurysms when those treated are compared with untreated aneurysms can only be determined by prospective randomized analyses. Unfortunately, none currently exist.

Lacking precise data on natural history, many investigators have focused on the relation of aneurysm size and expansion rate to the risk of rupture.

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Population-based studies suggest annual increases of approximately 0.2 cm in aneurysm diameters.[32,33] Referral-based studies using computed tomography (CT) and B-mode ultrasonography have recorded annual expansion rates of from 0.30 to 0.57 cm, or an average of 0.4 cm per year.[34-38] Large aneurysms, those more than 5 to 6 cm in diameter, expanded more rapidly than small ones.[32-36,38] Cronenwett and his associates noted that during an average follow-up period of 36 months, 9 percent of small aneurysms (mean diameter, 4 cm) ruptured; an additional 9 percent expanded.[36] Risk factors for rupture included the initial diameter of the aneurysm, elevated blood pressure, and the presence of chronic obstructive pulmonary disease. Although 15 to 20 percent of small aneurysms do not expand substantially, 80 percent increase progressively in diameter and approximately 20 percent increase by more than 0.5 cm per year. Unfortunately, it is impossible to predict the rate of expansion in any one patient; some aneurysms remain stable for years and then expand rapidly.

From clinical studies, it appears that for abdominal aortic aneurysms less than 4.0 cm in diameter the risk of rupture is approximately 2 percent.[36,39] From 25 to 41 percent of aneurysms larger than 5.0 cm in diameter rupture within five years.[32,39-41] A recent population-based study reporting a very low rupture rate for small aneurysms has been questioned, because one quarter of the patients with aneurysms smaller than 5 cm underwent surgery, and five patients who had documented aneurysm leakage within 48 hours of ultrasound examination were excluded from analysis.[32,39,42,43]

Data on the risk of rupture for aneurysms 4 to 5 cm in diameter are sparse, but such lesions have been reported to have five-year rupture rates of 3 to 12 percent.[40,41,44]

Diagnosis and Screening

Diagnosis

Abdominal ultrasonography detects aneurysms with a sensitivity that approaches 100 percent.[45] Both longitudinal and transverse aortic diameters can be measured, and intravenous contrast agents or ionizing radiation is not required. Measurements of aneurysm size are reproducible within a range of 0.6 cm. The success of sonography is highly dependent on the technologist, however, and it may not be possible in obese patients, those with excessive bowel gas, or those with periaortic disease. Furthermore, ultrasonography yields imprecise data for the surgeon contemplating aortic reconstruction, because it cannot accurately document the proximal or distal extent of the aneurysm. Similarly, it does not image the visceral vessels with sufficient detail to be useful in planning the operation.

CT is highly sensitive and specific for the identification of abdominal aortic aneurysms and may in fact be more accurate in estimating their size than ultrasonography.[46] CT also provides information on the shape of the aneurysm and the anatomical relations of the visceral and renal vessels.[47,48] Like sonography, CT imaging may be inaccurate in the evaluation of a tortuous aorta, and it may suggest juxtarenal or suprarenal extension when this is not the case. Other disadvantages of CT are the need for intravenous contrast material and the use of ionizing radiation. Since it is less widely available and more costly than ultrasound, CT is not recommended for screening or as a routine preoperative study. If, however, a plan of watchful waiting is adopted with a decision to operate on the basis of precise increases in aneurysm diameter, then CT imaging, because of its accuracy among different studies, is appropriate for sequential follow-up.

Magnetic resonance imaging (MRI) may be a better method of imaging than either ultrasonography or CT, both for accurate aneurysm measurements and for views of the relevant vascular anatomy.[49,50] MRI provides coronal, transverse, and sagittal views of the aorta that define the aneurysm and its relations to aortic branch vessels with a clarity almost equaling that of contrast aortography. Furthermore, MRI is noninvasive and does not require ionizing radiation or the injection of contrast material. Unfortunately, MRI has limited application because it is expensive, is not widely available, is imprecise in identifying associated occlusive arterial disease, and is contraindicated in patients with pacemakers and those in whom ferromagnetic clips have been used. Consequently, at the present time MRI offers no practical advantages over sonography or CT.

Once an abdominal aortic aneurysm has been identified and the patient is deemed a candidate for surgery, many surgeons request conventional biplanar aortography or intraarterial digital subtraction aortography in order to plan the operation. The use of aortography for diagnosis or determination of aneurysm size is inappropriate because mural thrombi may lead to an underestimation of size or even a misdiagnosis of the presence of an aneurysm. There is debate about the need for preoperative aortography; some surgeons use this procedure routinely, some almost never, and others selectively.[51,52] Provided there are no compelling contraindications, aortography should be performed in the case of suspected suprarenal or juxtarenal aneurysms, suspected renovascular hypertension or ischemic nephropathy, suspected mesenteric-artery stenosis, and associated iliofemoral arterial occlusive disease.

In summary, ultrasonography should be used for aneurysm detection and sequential follow-up, CT when ultrasonography is not possible and precise sizing is required, and aortography to acquire anatomical information useful for aortic reconstruction, but only after the decision to operate has been made. For the majority of patients, only abdominal ultrasonography followed by aortography is necessary.

Screening

Some have questioned the cost effectiveness of random screening of the population for abdominal aortic

aneurysms.[53] Nevertheless, interest has continued in refining screening programs to identify patients for possible operation before rupture occurs. Society's views of cost effectiveness are based on the value of lives saved as compared with the expense of screening.[54] From a theoretical screening model of a population of 100,000, it has been estimated that 1500 lives could be saved at a cost of $78,000 per life saved.[55] Selective screening may be cost effective, especially if it focuses on the patients at highest risk, including patients between the ages of 55 and 80, those with hypertension, those with aneurysms of the femoral or popliteal artery, and those with a family history of abdominal aortic aneurysm.[56,57]

Indications for Operation

The decision to operate on a patient must be made on an individual basis, since all aneurysms are potentially lethal and rates of expansion and frequencies of rupture are unpredictable. Most vascular surgeons recommend repair for all symptomatic or ruptured abdominal aortic aneurysms and for all asymptomatic aneurysms more than 5 cm in diameter, provided coexisting conditions do not preclude operation.[35-37,41,44,58] Repair of aneurysms less than 4 cm in diameter has occasionally been suggested.[33] For those measuring 4 to 5 cm in diameter operation is controversial, although aneurysms of this size may have a rupture rate as high as 6 percent per year.[34] Data from a Markov decision-model analysis suggested that early operation was preferred to watchful waiting for aneurysms 4 to 5 cm in diameter.[59] Some recommend operation for aneurysms 4 cm or more in diameter.[42,43,60] This perspective was supported by a study in which 74 percent of patients under the age of 69 who had aneurysms more than 4 cm in diameter at entry eventually had surgery.[37] This suggests that patients at good risk who have reasonable life expectancies and small aneurysms will eventually require aortic reconstruction.

A report by an ad hoc committee of the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery detailed currently accepted indications for operation.[42] Repair of asymptomatic aneurysms more than 4 cm in diameter or twice the diameter of the normal infrarenal aorta was recommended, provided there are no compelling contraindications as a result of coexisting illnesses. If elective repair is contraindicated, repeat ultrasound examination every six months was suggested for aneurysms 4 to 5 cm in diameter and every three months for larger ones. If expansion of 0.5 cm or more is documented, operation should be seriously considered.

Contraindications to elective aortic reconstruction include myocardial infarction within the past six months, intractable congestive heart failure, intractable angina pectoris, severe pulmonary insufficiency with dyspnea at rest, severe chronic renal insufficiency, incapacitating residual effects from stroke, and a life expectancy of less than two years. These contraindications are largely ignored in the case of immediate life-threatening complications, but again, the risks for each patient must be considered individually.

Preoperative Evaluation

Coexisting conditions, particularly coronary artery disease, must be identified and addressed preoperatively if one is to achieve optimal results. Hertzer's comprehensive analysis of aortic reconstruction for aneurysmal disease documented that myocardial infarction accounted for 37 percent of early postoperative deaths.[61] Furthermore, 39 percent of deaths within five years of operation resulted from coronary artery disease. In another study that included 263 patients with abdominal aortic aneurysms who underwent routine coronary arteriography before elective aortic reconstruction, severe correctable coronary artery disease was identified in 31 percent.[62] It is noteworthy that surgically correctable disease was present in 18 percent of patients in whom there was no clinical suspicion of coronary artery disease. The authors suggested that patients with symptomatic coronary artery disease should undergo coronary arteriography, with the implication that myocardial revascularization should precede aortic reconstruction.

Many reserve coronary arteriography for patients with clinically relevant coronary artery disease.[63,64] Those favoring a selective approach argue that patients at risk for ischemic myocardial events during and after aortic reconstruction can be reliably identified on the basis of clinical criteria alone.[63] In patients without clinical manifestations of coronary artery disease, different centers have different approaches to preoperative evaluation. Noninvasive studies such as stress electrocardiography, continuous Holter monitoring, stress echocardiography, exercise thallium myocardial imaging, or other radionuclide studies may be indicated in some subgroups of patients. Decisions to undertake coronary arteriography and myocardial revascularization should be based on the results of these studies in conjunction with cardiology consultation.[65,66]

Other coexisting conditions, including pulmonary and renal disease, must also be identified and addressed preoperatively. Marginal pulmonary function, particularly values less than 50 percent of predicted for vital capacity and forced expiratory volume in one second, may preclude elective aortic reconstruction. Marginal renal function, as indicated by serum creatinine elevations above 3 mg per deciliter (229 μmol per liter), must be evaluated and corrected, if possible. Correctable renal-artery occlusive disease may contribute to impaired renal function in certain patients with abdominal aortic aneurysms.

Rupture of Abdominal Aortic Aneurysms

If a person with an abdominal aortic aneurysm lives long enough, rupture of the aneurysm is inevitable. Although the overall mortality after rupture may exceed 90 percent, approximately 50 percent of those who reach the hospital alive survive. Furthermore, the

Table 1. Results of Surgery for Nonruptured Abdominal Aortic Aneurysm.

Study	Year	Study Period	No. of Patients	No. of Deaths	Mortality (%)
Crawford et al.[78]	1981	1955–1980	860	41	4.8
McCabe et al.[79]	1981	1972–1977	364	9	2.5
Diehl et al.[80]	1983	1974–1978	350	18	5.1
Hertzer et al.[75]	1984	1978–1981	840	55	6.5
Donaldson et al.[81]	1985	1972–1983	476	24	5.0
Reigel et al.[64]	1987	1980–1985	499	14	2.8
Green et al.[82]	1989	1983–1987	379	8	2.1
Johnston[83]	1989	1986	666	32	4.8
Leather et al.[84]	1989	Not stated	299	11	3.7
Sicard et al.[85]	1989	1983–1988	213	3	1.4
Golden et al.[63]	1990	1973–1989	500	8	1.6
AbuRahma et al.[86]	1991	1983–1987	332	12	3.6
This study	1992	1980–1989	710	25	3.5
All	—	—	6488	260	4.0

long-term survival rate is not significantly different from that of a general population matched for age and sex or that of patients undergoing elective repair.[67]

Some have argued for withholding operation in selected patients with ruptured aneurysms, particularly those with preoperative cardiac arrest, those with hematocrit values less than 25 percent, those with persistent hypotension, and octogenarians.[68] The prevailing view among surgeons, however, is that operation should not be denied, since it provides the only hope for survival and a survival rate of 25 percent can be expected among these patients.[69-71]

Although the diagnosis of a ruptured aneurysm may be obvious, the classic triad of hypotension, back pain, and a pulsatile abdominal mass may be present in only half of patients.[67] In the presence of a known abdominal aortic aneurysm, however, any of these symptoms mandates immediate operation without confirmatory tests such as ultrasonography or CT imaging. Misdiagnosis may occur in up to 30 percent of patients, the most common conditions being renal colic, diverticulitis, and gastrointestinal hemorrhage.[72]

Table 2. Results of Surgery for Ruptured Abdominal Aortic Aneurysm.

Study	Year	Study Period	No. of Patients	No. of Deaths	Mortality (%)
Crawford et al.[78]	1981	1955–1980	60	14	23
McCabe et al.[79]	1981	1972–1977	73	38	52
Wakefield et al.[87]	1982	1964–1980	116	60	52
Hoffman et al.[88]	1982	1975–1979	152	58	38
Donaldson et al.[81]	1985	1972–1983	81	35	43
Meyer et al.[89]	1986	Not stated	97	45	46
Shackleton et al.[90]	1987	1975–1985	106	43	41
Chang et al.[91]	1990	1983–1989	63	16	25
Ouriel et al.[92]	1990	1979–1988	243	133	55
Sullivan et al.[93]	1990	1978–1989	69	24	35
AbuRahma et al.[94]	1991	1983–1987	73	45	62
Harris et al.[71]	1991	1980–1989	113	72	64
Johansen et al.[68]	1991	1980–1989	180	124	69
Gloviczki et al.[70]	1992	1980–1989	214	97	45
This study	1992	1980–1989	91	41	45
All	—	—	1731	845	49

Most aneurysms rupture into the left retroperitoneum. Although the patient may have hypovolemic shock, exsanguination is not the rule because of clotting and the tamponade effect of the retroperitoneum. As long as the patient is conscious and has adequate peripheral perfusion, euvolemic resuscitation should be deferred until the rupture is controlled in the operating room. Euvolemic resuscitation and raising of the blood pressure without control of the aneurysm may lead to loss of retroperitoneal tamponade, with further bleeding, profound hypotension, and death. When the diagnosis is unclear and the patient is hemodynamically stable, abdominal ultrasonography will document an aneurysm, and CT imaging may prove useful in identifying rupture.[45,73] It must be emphasized, however, that in an unstable patient with a suspected ruptured aneurysm, immediate operation without confirmatory testing or full resuscitation is mandatory.

Results of Aortic Reconstruction

Prosthetic-graft replacement of the diseased aorta is the current standard of care. Although nonresective therapy such as thrombosis of the aneurysm or aortic ligation with axillofemoral bypass has been suggested in patients at high risk, these techniques have not proved efficacious and have been abandoned because the procedures are not without risk and, even after transluminal thrombosis, rupture may occur. Treatment by transfemoral intraluminal graft implantation has recently been proposed[74] but will require adequate clinical testing before it is adopted.

Elective aortic reconstruction has become a safe operation. Coupled with improved preoperative preparation and postoperative care, technical advances in surgical and anesthetic management have reduced operative mortality over four decades from approximately 20 to 4 percent. The results of treatment depend on the timing of the operation, the condition of the patient, and the technical complexity of the operative procedure. The experience of the surgeon greatly influences results; those with more experience and those who work at major centers usually have the best results.[75-77]

A review of contemporary outcome data from representative North American reports dating from 1981 revealed excellent results. Only reports including more than 200 patients undergoing repair of nonruptured aneurysms and those including more than 50 patients undergoing repair of ruptured aneurysms were included (Tables 1 and 2). All were referral-based studies, since no population-based studies of similar size have been reported. Operative mortality rates for a total of 6488 nonruptured aneurysms ranged from 1.4 to 6.5 percent and averaged 4.0 percent (median, 3.6 percent). Mortality rates for 1731 ruptured aneurysms ranged from 23 to 69 percent and averaged 49 percent (median, 45 percent). The 12-fold increase in operative deaths for ruptured as compared with nonruptured aneurysms clearly suggests that more emphasis should be placed on identifying and repairing asymptomatic lesions. Survival after repair

Table 3. Late Survival after Repair of an Abdominal Aortic Aneurysm.

Study	Year	Study Period	No. of Patients	Survival Rate (%)		
				1 yr	5 yr	10 yr
Crawford et al.[78]*	1981	1955–1980	860	95	62	38
Hollier et al.[95]*	1984	1970–1975	1066	91	68	41
Reigel et al.[64]	1987	1980–1985	499	95	74	—
This study*	1992	1980–1989	801	87	64	—
All†	—	—	3226	92	67	40

*Ruptured aneurysms were included in this study

†Survival rates shown are averages for the four studies

in 3226 patients averaged 92 percent at one year and 67 percent at five years (Table 3). As expected, patients without clinical coronary artery disease fared better than those with such disease.

Early complications after elective operations include cardiac events with ischemia, arrhythmia, and congestive heart failure (15 percent), pulmonary insufficiency (8 percent), renal damage (6 percent), bleeding (4 percent), distal thromboembolism (3 percent), and wound infection (2 percent).[83] Ischemic colitis, stroke, and paraplegia or paraparesis are distinctly rare clinical complications. The precise frequency of postoperative sexual dysfunction remains unknown because such data are seldom recorded.

Late postoperative complications, including graft infection, aortoenteric fistula, graft occlusion, and anastomotic aneurysms, must be acknowledged when overall survival rates are assessed. These complications occur an average of three to five years after aortic reconstruction. Such late complications, although uncommon, may add an additional 2 percent to overall mortality.[96] Consequently, the treatment mortality for patients undergoing operation for asymptomatic aneurysms is approximately 6 percent. This is far better than the 25 to 40 percent five-year rupture rate for untreated aneurysms, with 90 percent mortality for aneurysms 5 cm or larger.

The available data indicate that identification and early aortic reconstruction for abdominal aortic aneurysms 5 cm or more in diameter will save lives and improve the quality of life substantially. Until data from prospective randomized studies are available, however, it is important to consider each patient individually, because some with aneurysms 5 cm or less in diameter will require operation, whereas others with aneurysms 5 cm or more in diameter may not.

References

1. Dubost C, Allary M, Oeconomos N. Resection of an aneurysm of the abdominal aorta: reestablishment of the continuity by a preserved human arterial graft, with result after five months. Arch Surg 1952;64:405-8.
2. Johnston KW, Rutherford RB, Tilson MD, Shah DM, Hollier L, Stanley JC. Suggested standards for reporting on arterial aneurysms. J Vasc Surg 1991;13:452-8.
3. National Center for Health Statistics. Vital statistics of the United States, 1988. Vol. 2. Mortality. Part A. Washington, D.C.: Government Printing Office, 1991. (DHHS publication no. (PHS) 91-1101.)
4. National Center for Health Statistics, Graves EJ. Detailed diagnoses and procedures, National Hospital Discharge Survey, 1988. Vital and health statistics. Series 13. No. 107. Washington, D.C.: Government Printing Office, 1991. (DHHS publication no. (PHS) 91-1768.)
5. Ingoldby CJH, Wujanto R, Mitchell JE. Impact of vascular surgery on community mortality from ruptured aortic aneurysms. Br J Surg 1986;73:551-3.
6. Thomas PRS, Stewart RD. Abdominal aortic aneurysm. Br J Surg 1988;75:733-6.
7. Johansson G, Swedenborg J. Ruptured abdominal aortic aneurysms: a study of incidence and mortality. Br J Surg 1986;73:101-3.
8. Melton LJ III, Bickerstaff LK, Hollier LH, et al. Changing incidence of abdominal aortic aneurysms: a population-based study. Am J Epidemiol 1984;120:379-86.
9. Bickerstaff LK, Hollier LH, Van Peenen HJ, Melton LJ III, Pairolero PC, Cherry KJ. Abdominal aortic aneurysms: the changing natural history. J Vasc Surg 1984;1:6-12.
10. Bengtsson H, Bergqvist D, Sternby NH. Increasing prevalence of abdominal aortic aneurysms: a necropsy study. Eur J Surg 1992;158:19-23.
11. Breckwoldt WL, Mackey WC, O'Donnell TF Jr. The economic implications of high-risk abdominal aortic aneurysms. J Vasc Surg 1991;13:798-804.
12. Pasch AR, Ricotta JJ, May AG, Green RM, DeWeese JE. Abdominal aortic aneurysm: the case for elective resection. Circulation 1984;70:Suppl I: I-1–I-4.
13. Sumner DS, Hokanson DE, Strandness DE Jr. Stress-strain characteristics and collagen-elastin content of abdominal aortic aneurysms. Surg Gynecol Obstet 1970;130:459-66.
14. Dobrin PB, Baker WH, Gley WC. Elastolytic and collagenolytic studies of arteries: implications for the mechanical properties of aneurysms. Arch Surg 1984;119:405-9.
15. Campa JS, Greenhalgh RM, Powell JT. Elastin degradation in abdominal aortic aneurysms. Atherosclerosis 1987;65:13-21.
16. Cohen JR, Mandell C, Margolis I, Chang J, Wise L. Altered aortic protease and antiprotease activity in patients with ruptured abdominal aortic aneurysms. Surg Gynecol Obstet 1987;164:355-8.
17. Cohen JR, Mandell C, Chang JB, Wise L. Elastin metabolism of the infrarenal aorta. J Vasc Surg 1988;7:210-4.
18. Menashi S, Campa JS, Greenhalgh RM, Powell JT. Collagen in abdominal aortic aneurysm: typing, content, and degradation. J Vasc Surg 1987;6:578-82.
19. Brophy CM, Marks WH, Reilly JM, Tilson MD. Decreased tissue inhibitor of metalloproteinases (TIMP) in abdominal aortic aneurysm tissue: a preliminary report. J Surg Res 1991;50:653-7.
20. Rowe DW, McGoodwin EB, Martin GR, Grahn D. Decreased lysyl oxidase activity in the aneurysm-prone, mottled mouse. J Biol Chem 1977;252:939-42.
21. Zarins CK, Runyon-Hass A, Zatina MA, Lu CT, Glagov S. Increased collagenase activity in early aneurysmal dilatation. J Vasc Surg 1986;3:238-48.
22. Johansen K, Koepsell T. Familial tendency for abdominal aortic aneurysms. JAMA 1986;256:1934-6.
23. Darling RC III, Brewster DC, Darling RC, et al. Are familial abdominal aortic aneurysms different? J Vasc Surg 1989;10:39-43.
24. Webster MW, St Jean PL, Steed DL, Ferrell RE, Majumder PP. Abdominal aortic aneurysm: results of a family study. J Vasc Surg 1991;13:366-72.
25. Norrgard O, Rais O, Angquist KA. Familial occurrence of abdominal aortic aneurysms. Surgery 1984;95:650-6.
26. Tilson MD, Seashore MR. Fifty families with abdominal aortic aneurysms in two or more first-order relatives. Am J Surg 1984;147:551-3.
27. Powell JT, Bashir A, Dawson S, et al. Genetic variation on chromosome 16 is associated with abdominal aortic aneurysm. Clin Sci 1990;78:13-6.
28. Kontusaari S, Tromp G, Kuivaniemi H, Romanic AM, Prockop DJ. A mutation in the gene for type III procollagen (COL3A1) in a family with aortic aneurysms. J Clin Invest 1990;86:1465-73.
29. Tilson MD. Status of research on abdominal aortic aneurysm disease. J Vasc Surg 1989;9:367-9.
30. Estes JE Jr. Abdominal aortic aneurysm: a study of one hundred and two cases. Circulation 1950;2:258-64.
31. Szilagyi DE, Smith RF, DeRusso FJ, Elliott JP, Sherrin FW. Contribution of abdominal aortic aneurysmectomy to prolongation of life. Ann Surg 1966;164:678-99.
32. Nevitt MP, Ballard DJ, Hallett JW Jr. Prognosis of abdominal aortic aneurysms: a population-based study. N Engl J Med 1989;321:1009-14.
33. Collin J, Araujo L, Walton J. How fast do very small abdominal aortic aneurysms grow? Eur J Vasc Surg 1989;3:15-7.
34. Bernstein EF, Chan EL. Abdominal aortic aneurysm in high-risk patients: outcome of selective management based on size and expansion rate. Ann Surg 1984;200:255-63.
35. Delin A, Ohlsen H, Swedenborg J. Growth rate of abdominal aortic aneurysms as measured by computed tomography. Br J Surg 1985;72:530-2.
36. Cronenwett JL, Murphy TF, Zelenock GB, et al. Actuarial analysis of variables associated with rupture of small abdominal aortic aneurysms. Surgery 1985;98:472-83.
37. Brown PM, Pattenden R, Gutelius JR. The selective management of small abdominal aortic aneurysms: the Kingston Study. J Vasc Surg 1992;15:21-7.
38. Guirguis EM, Barber GG. The natural history of abdominal aortic aneurysms. Am J Surg 1991;162:481-3

39. Ouriel K, Green RM, Donayre C, Shortell CK, Elliott J, DeWeese JA. An evaluation of new methods of expressing aortic aneurysm size: relationship to rupture. J Vasc Surg 1992;15:12-20.
40. Limet R, Sakalihassan N, Albert A. Determination of the expansion rate and incidence of rupture of abdominal aortic aneurysms. J Vasc Surg 1991;14: 540-8.
41. Johansson G, Nydahl S, Olofsson P, Swedenborg J. Survival of patients with abdominal aortic aneurysms: comparison between operative and non-operative management. Eur J Vasc Surg 1990;4:497-502.
42. Hollier LH, Taylor LM, Ochsner J. Recommended indications for operative treatment of abdominal aortic aneurysms: report of a subcommittee of the Joint Council of the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery. J Vasc Surg 1992;15:1046-56.
43. Crawford ES, Hess KR. Abdominal aortic aneurysm. N Engl J Med 1989; 321:1040-2.
44. Glimaker H, Holmberg L, Elvin A, et al. Natural history of patients with abdominal aortic aneurysm. Eur J Vasc Surg 1991;5:125-30.
45. LaRoy LL, Cormier PJ, Matalon TAS, Patel SK, Turner DA, Silver B. Imaging of abdominal aortic aneurysms. AJR Am J Roentgenol 1989; 152:785-92.
46. Ellis M, Powell JT, Place J, et al. The limitation of ultrasound in surveillance of small abdominal aortic aneurysms. In: Greenhalgh RM, Mannick JA, Powell JT, eds. The cause and management of aneurysms. London: W.B. Saunders, 1990:117-21.
47. Todd GJ, Nowygrod R, Benvenisty A, Buda J, Reemtsma K. The accuracy of CT scanning in the diagnosis of abdominal and thoracoabdominal aortic aneurysms. J Vasc Surg 1991;13:302-10.
48. Gomes MN, Choyke PL. Improved identification of renal arteries in patients with aortic aneurysms by means of high-resolution computed tomography. J Vasc Surg 1987;6:262-8.
49. Ruff SJ, Watson MR. Magnetic resonance imaging versus angiography in the preoperative assessment of abdominal aortic aneurysms. Am J Surg 1988;155:651-4.
50. Amparo EG, Hoddick WK, Hricak H, et al. Comparison of magnetic resonance imaging and ultrasonography in the evaluation of abdominal aortic aneurysms. Radiology 1985;154:451-6.
51. Campbell JJ, Bell DD, Gaspar MR. Selective use of arteriography in the assessment of aortic aneurysm repair. Ann Vasc Surg 1990;4:419-23.
52. Baur GM, Porter JM, Eidemiller LR, Rosch J, Keller F. The role of arteriography in abdominal aortic aneurysm. Am J Surg 1978;136:184-9.
53. Allen PIM, Gourevitch D, McKinley J, Tudway D, Goldman M. Population screening for aortic aneurysms. Lancet 1987;2:736.
54. Bengtsson H, Bergqvist D, Jendteg S, Lindgren B, Persson U. Ultrasonographic screening for abdominal aortic aneurysm: analysis of surgical decisions for cost-effectiveness. World J Surg 1989;13:266-71.
55. Quill DS, Colgan MP, Sumner DS. Ultrasonic screening for the detection of abdominal aortic aneurysms. Surg Clin North Am 1989;69:713-20.
56. Webster MW, Ferrell RE, St Jean PL, Majumder PP, Fogel SR, Steed DL. Ultrasound screening of first-degree relatives of patients with an abdominal aortic aneurysm. J Vasc Surg 1991;13:9-14
57. Berridge DC, Griffith CD, Amar SS, Hopkinson BR, Makin GS. Screening for clinically unsuspected abdominal aortic aneurysms in patients with peripheral vascular disease. Eur J Vasc Surg 1989;3:421-2.
58. Cronenwett JL, Sargent SK, Wall MH, et al. Variables that affect the expansion rate and outcome of small abdominal aortic aneurysms. J Vasc Surg 1990;11:260-8.
59. Katz DA, Littenberg B, Cronenwett JL. Management of small abdominal aortic aneurysms: early surgery vs watchful waiting. JAMA 1992;268: 2678-86.
60. Bernstein EF. Discussion of: Cronenwett JL, Sargent SK, Wall MH, et al. Variables that affect the expansion rate and outcome of small abdominal aortic aneurysms. J Vasc Surg 1990;11:268-9.
61. Hertzer NR. Fatal myocardial infarction following abdominal aortic aneurysm resection: three hundred forty-three patients followed 6–11 years postoperatively. Ann Surg 1980;192:667-73.
62. Hertzer NR, Beven EG, Young JR, et al. Coronary artery disease in peripheral vascular patients: a classification of 1000 coronary angiograms and results of surgical management. Ann Surg 1984;199:223-33.
63. Golden MA, Whittemore AD, Donaldson MC, Mannick JA. Selective evaluation and management of coronary artery disease in patients undergoing repair of abdominal aortic aneurysms: a 16-year experience. Ann Surg 1990; 212:415-23.
64. Reigel MM, Hollier LH, Kazmier FJ, et al. Late survival in abdominal aortic aneurysm patients: the role of selective myocardial revascularization on the basis of clinical symptoms. J Vasc Surg 1987;5:222-7.
65. McEnroe CS, O'Donnell TF Jr, Yeager A, Konstam M, Mackey WC. Comparison of ejection fraction and Goldman risk factor analysis to dipyridamole-thallium 201 studies in the evaluation of cardiac morbidity after aortic aneurysm surgery. J Vasc Surg 1990;11:497-504.
66. Cambria RP, Brewster DC, Abbott WM, et al. The impact of selective use of dipyridamole-thallium scans and surgical factors on the current morbidity of aortic surgery. J Vasc Surg 1992;15:43-51.
67. Rohrer MJ, Cutler BS, Wheeler HB. Long-term survival and quality of life following ruptured abdominal aortic aneurysm. Arch Surg 1988;123:1213-7.
68. Johansen K, Kohler TR, Nicholls SC, Zierler RE, Clowes AW, Kazmers A. Ruptured abdominal aortic aneurysm: the Harborview experience. J Vasc Surg 1991;13:240-7.
69. Crawford ES. Ruptured abdominal aortic aneurysm. J Vasc Surg 1991;13: 348-50.
70. Gloviczki P, Pairolero PC, Mucha P Jr, et al. Ruptured abdominal aortic aneurysms: repair should not be denied. J Vasc Surg 1992;15:851-9.
71. Harris LM, Faggioli GL, Fiedler R, Curl GR, Ricotta JJ. Ruptured abdominal aortic aneurysms: factors affecting mortality rates. J Vasc Surg 1991;14: 812-20.
72. Marston WA, Ahlquist R, Johnson G Jr, Meyer AA. Misdiagnosis of ruptured abdominal aortic aneurysms. J Vasc Surg 1992;16:17-22.
73. Kvilekval KHV, Best IM, Mason RA, Newton GB, Giron F. The value of computed tomography in the management of symptomatic abdominal aortic aneurysms. J Vasc Surg 1990;12:28-33.
74. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg 1991;5:491-9.
75. Hertzer NR, Avellone JC, Farrell CJ, et al. The risk of vascular surgery in a metropolitan community: with observations on surgeon experience and hospital size. J Vasc Surg 1984;1:13-21.
76. Luft HS, Bunker JP, Enthoven AC. Should operations be regionalized? The empirical relations between surgical volume and mortality. N Engl J Med 1979;301:1364-9.
77. Veith FJ, Goldsmith J, Leather RP, Hannan EL. The need for quality assurance in vascular surgery. J Vasc Surg 1991;13:523-6.
78. Crawford ES, Saleh SA, Babb JW III, Glaeser DH, Vaccaro PS, Silvers A. Infrarenal abdominal aortic aneurysm: factors influencing survival after operation performed over a 25-year period. Ann Surg 1981;193:699-709.
79. McCabe CJ, Coleman WS, Brewster DC. The advantage of early operation for abdominal aortic aneurysm. Arch Surg 1981;116:1025-9.
80. Diehl JT, Cali RF, Hertzer NR, Beven EG. Complications of abdominal aortic reconstruction: an analysis of perioperative risk factors in 557 patients. Ann Surg 1983;197:49-56.
81. Donaldson MC, Rosenberg JM, Bucknam CA. Factors affecting survival after ruptured abdominal aortic aneurysm. J Vasc Surg 1985;2:564-70.
82. Green RM, Ricotta JJ, Ouriel K, DeWeese JA. Results of supraceliac aortic clamping in the difficult elective resection of infrarenal abdominal aortic aneurysm. J Vasc Surg 1989;9:124-34.
83. Johnston KW. Multicenter prospective study of nonruptured abdominal aortic aneurysms. II. Variables predicting morbidity and mortality. J Vasc Surg 1989;9:437-47.
84. Leather RP, Shah DM, Kaufman JL, Fitzgerald KM, Chang BB, Feustel PJ. Comparative analysis of retroperitoneal and transperitoneal aortic replacement for aneurysm. Surg Gynecol Obstet 1989;168:387-93.
85. Sicard GA, Allen BT, Munn JS, Anderson CB. Retroperitoneal versus transperitoneal approach for repair of abdominal aortic aneurysms. Surg Clin North Am 1989;69:795-806.
86. AbuRahma AF, Robinson PA, Boland JP, et al. Elective resection of 332 abdominal aortic aneurysms in a southern West Virginia community during a recent five-year period. Surgery 1991;109:244-51.
87. Wakefield TW, Whitehouse WM Jr, Wu SC, et al. Abdominal aortic aneurysm rupture: statistical analysis of factors affecting outcome of surgical treatment. Surgery 1982;91:586-96.
88. Hoffman M, Avellone JC, Plecha FR, et al. Operation for ruptured abdominal aortic aneurysms: a community-wide experience. Surgery 1982;91:597-602
89. Meyer AA, Ahlquist RE Jr, Trunkey DD. Mortality from ruptured abdominal aortic aneurysms: a comparison of two series. Am J Surg 1986;152:27-33.
90. Shackleton CR, Schechter MT, Bianco R, Hildebrand HD. Preoperative predictors of mortality risk in ruptured abdominal aortic aneurysm. J Vasc Surg 1987;6:583-9.
91. Chang BB, Shah DM, Paty PSK, Kaufman JL, Leather RP. Can the retroperitoneal approach be used for ruptured abdominal aortic aneurysms? J Vasc Surg 1990;11:326-30.
92. Ouriel K, Geary K, Green RM, Fiore W, Geary JE, DeWeese JA. Factors determining survival after ruptured aortic aneurysm: the hospital, the surgeon, and the patient. J Vasc Surg 1990;11:493-6.
93. Sullivan CA, Rohrer MJ, Cutler BS. Clinical management of the symptomatic but unruptured abdominal aortic aneurysm. J Vasc Surg 1990;11:799-803.
94. AbuRahma AF, Woodruff BA, Lucente FC, Stuart SP, Boland JP. Factors affecting survival of patients with ruptured abdominal aortic aneurysm in a West Virginia community. Surg Gynecol Obstet 1991;172:377-82.
95. Hollier LH, Plate G, O'Brien PC, et al. Late survival after abdominal aortic aneurysm repair: influence of coronary artery disease. J Vasc Surg 1984;1: 290-9.
96. Lederle FA. Management of small abdominal aortic aneurysms. Ann Intern Med 1990;113:731-2.

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	Tefzel	Liner for pulse generators
	Teflon coating	Splitable sheath
	Kapton/Pyralux	All Flex circuits and coils
	Teflon/Tefzel	Batteries
	LTCC and Pastes	Hybrids (circuit boards)
	Films	Capacitors
	Tyvek	Packaging
	Dapton Tape	Device Packaging
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[From the Wall Street Journal, Dec. 3, 1993]

SUITS BY FIRMS EXCEED THOSE BY INDIVIDUALS

(By Milo Geyelin)

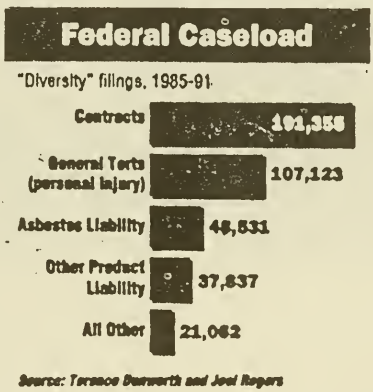
Businesses may be their own worst enemies when it comes to the so-called litigation explosion.

Preliminary data in the first-ever study of litigation patterns of Fortune 1000 companies show that businesses' contract disputes with each other constitute the largest single category of lawsuits filed in federal court. Trailing behind are personal-injury suits and product-liability cases brought by individuals.

This result—while limited to federal courts—seems to challenge companies' frequent claims that personal-injury plaintiffs' lawyers are the main engines of litigation in America. And, it may force some companies to review their own penchant for using the courts to resolve commercial disputes.

The finding is part of an ongoing study by University of Wisconsin sociologist Joel Rogers and RAND Institute for Civil Justice senior researcher Terence Dunworth. Ultimately, by looking at 1,908 companies that have been ranked among the Fortune 1000 from 1971 to 1991, the study will chart federal trends industry by industry and company by company.

The results so far, presented in draft form at a symposium at the University of Wisconsin's Institute for Legal Studies two weeks ago, also show that the once-steady annual increases in overall legal filings involving Fortune 1000 companies peaked in 1987 and have declined 21% since then. Similarly, business litigation involving smaller companies and individuals peaked in 1986 and has since dropped 12%.



When cases are broken down by category, the study shows that labor and civil-rights claims have increased in recent years. So have filings involving a single product such as asbestos-related injuries. Otherwise, product-liability suits against Fortune 1000 companies have actually dropped, from a high of 3,500 in 1985 to 1,500 in 1991.

"I know that business doesn't want to hear that, but these data don't seem to lie," says Mr. Rogers.

The reasons for the various litigation patterns are far from clear, however. For example, says Mr. Rogers, the high incidence of commercial legal disputes among businesses may be the result of their litigiousness or may just reflect the increase in the number of contracts in effect—and thus potentially subject to dispute—in a growing economy.

In either event, the results suggest that by pointing the finger at plaintiffs' lawyers, business leaders and advocates of legal reform may be bypassing other contributors to the overburdened civil-justice system, at least in the federal courts.

In response to the study's finding, legal-reform advocates voiced skepticism about what the federal-court results may mean. "The overwhelming majority of product-liability claims are filed in state courts," says Victor Schwartz, a lawyer-lobbyist in Washington, D.C., who represents backers of a proposed federal law to rein in some product-liability claims.

State courts are generally regarded by plaintiffs' lawyers as friendlier forums for personal-injury and product-liability claims than federal courts, and most suits

against local businesses and manufacturers would more likely be filed in local courts. But comprehensive state-court data are nearly impossible to compile. So studies of state systems have been confined to a limited number of courts. Thus, few useful comparisons can be made with the federal numbers.

Responds RAND researcher Mr. Dunworth: "It's better to light a candle than to curse the darkness. Even if that's all you're doing by looking at federal courts, you're further ahead than you were."

Messrs. Rogers and Dunworth relied on a computer database of more than four million federal lawsuits between 1971 and 1991 to identify 2.48 million suits that involved at least one business entity. Fortune 1000 companies were involved either as plaintiffs or defendants in 457,358 of those suits, or nearly 20%, according to the study. Not surprisingly, they were defendants in virtually all personal-injury cases (95%) and in most labor and civil-rights cases (85%). In contract disputes, Fortune 1000 companies sued each other as often as they were sued.

To get a more detailed look at how Fortune 1000 companies compared with other litigants—such as other businesses, governments and individuals—the study examined 405,908 cases that landed in federal court solely because the parties came from different states, thus creating so-called diversity of jurisdiction. Since 1985, records in such cases have indicated whether either party is a corporation, large or small.

According to these records, 43% of the civil lawsuits involving Fortune 1000 companies between 1985 and 1991 were contract disputes. For smaller corporations, the percentage was even higher—51%. Taken together, business disagreements, whether among individuals, companies or corporations, made up nearly half of all federal litigation in this sample. Federal suits over contracts outpaced any other single category of litigation.

Yet even these cases are on the decline now. Contract lawsuits peaked at 10,253 in 1987 and dropped 30% to 7,182 in 1991. A key reason, corporate legal experts say, is companies' growing willingness to settle disputes through arbitration and mediation. "When you have businesses suing businesses," says Shelby R. Rogers Jr., general counsel for the Texas Medical Association, in Houston. "you find that getting to the courthouse takes a number of years . . . and as a result we see many more businesses going to different forms of alternative dispute resolution."

But Mr. Rogers, of the Texas Medical Association, says he is yet to be persuaded that federal litigation trends bear any relation to what's happening in jurisdictions such as the Texas state courts, long regarded as among the most pro-plaintiff in the country. And even Mr. Dunworth concedes there's "a great deal of uncertainty about what's taken place in state courts." But he adds: "if there are significant trends at work (generally), they surely must be evident in federal courts."

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